Author:
Fitzsimons, Kate J

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Physical activity and cardiorespiratory fitness in adults with newly-diagnosed type 2 diabetes : associations with glycaemic control and cardiovascular risk factors

Physical activity and cardiorespiratory fitness in adults with newly-diagnosed type 2 diabetes: Associations with glycaemic control and cardiovascular risk factors

Kate J Fitzsimons

Department of Exercise, Nutrition and Health Sciences, University of Bristol

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Abstract

Background: Type 2 diabetes mellitus (T2D) has become a worldwide epidemic. Although physical activity and cardiorespiratory fitness (CRF) are considered to be beneficial for diabetes management, there are no published studies reporting their relative importance, or interaction effects, in relation to glycaemic control (HBA_{1c}) and cardiovascular risk factors, which are strong predictors of diabetes-related morbidity and mortality. The Early ACTID Study is a randomised controlled trial of *diet plus exercise* vs. *diet alone* and *usual care* in adults with type 2 diabetes, who were recruited five to eight months after diagnosis.

Purpose: The purpose of this study was to 1) develop intervention materials to facilitate change in physical activity levels, 2) describe objectively measured habitual physical activity, 3) examine change in physical activity over six months, 4) explore the use of pedometers and diaries to monitor daily physical activity over a six-month period, 5) describe CRF levels, and 6) explore the independent and interactive cross-sectional associations of physical activity and CRF with HbA_{1c} and the clustering of cardiovascular risk factors (i.e., metabolic syndrome) among adults with recently diagnosed T2D recruited to the Early ACTID Study.

Methods: Anthropometric, physiological and biochemical measures were performed using standardised procedures at baseline and six months post randomisation. The IDF definition of the metabolic syndrome was used to assess the clustering of cardiovascular risk factors. Habitual physical activity was measured objectively using the ActiGraph GT1M accelerometer, which was worn during all waking hours for seven days. Activity volume was calculated as accelerometer counts per minute (CPM), and time spent in moderate to vigorous physical activity (MVPA) was calculated using a cut-point of 2100 CPM. CRF was estimated using a submaximal 1-mile track walk test. VO_{2max} was predicted from time taken to complete 1-mile, heart rate at completion (Polar T61 HRM), weight, age and gender using standard Rockport walking test regression equations. Cross-sectional associations with HbA_{1c} and metabolic syndrome status were examined at baseline and six months. The use of pedometers and physical activity diaries over a six-month period was evaluated in the *diet plus exercise* group in order to assess their acceptability to people with T2D.

Results: Three-hundred and forty participants (207 men, 133 women), aged 59.3±10.38 years, were recruited to the study. Of these, 54% met the IDF metabolic syndrome criteria. Accelerometer data were obtained from 321 participants who recorded a mean of 243±97.17 CPM and 21.57±17.62 minutes of MVPA per day. Just 14% of participants accumulated ≥30 minutes of MVPA on at least five out of seven days. Ten percent of men and 14% of women accumulated <30 minutes of MVPA over seven days and were classified as sedentary. At six months, 22% of *diet plus exercise* participants accumulated ≥30 minutes of MVPA on at least five days compared to 15% of those in the *non-exercise* groups (χ^2 (1)=6.69, P=0.01).

Compliance with keeping daily physical activity records among *diet plus exercise* participants was 86.3% over a six month period. Compared with baseline, the number of self-reported daily steps was significantly higher at six months (6445±2502 vs. 7405±2716, t(102)=3.80, P<0.001) and a greater proportion of participants reported accumulating 10,000 steps per day (7.4% vs. 17.5%, χ^2 (1)=15.16, P=0.02).

Fitness data were calculated for 144 men and 93 women who were not prescribed beta blockers and who completed the 1-mile walk test within the parameters of the estimation equation. Mean $VO_{2max\ pred}$ was 30.03±7.55ml kg min^{-1} for men and 20.59±6.35ml kg min^{-1} for women. Physical activity volume (CPM) was a stronger predictor of $VO_{2max.pred}$ than time spent in MVPA (R^2=.15 vs. .10, P<0.001), and explained a greater proportion of the variance in $VO_{2max\ pred}$ in women than men (R^2=.28 vs. .14%, P<0.001).

Physical activity and CRF were not associated with glycaemic control but were predictors of the metabolic syndrome. Compared to those not accumulating ≥30 minutes of MVPA on ≥5 days per week, the odds ratio (OR) of the metabolic syndrome associated with meeting this recommended level of activity was .344 (95% CI .162 to .730). Similarly, when participants were categorised below or above the gender-specific $VO_{2max\ pred}$ median, the odds ratio of the metabolic syndrome for those in the higher-fit group compared to the lower-fit group was .298 (95% CI .174 to .509). When examined by gender, higher physical activity and fitness levels were more protective against the metabolic syndrome in women than in men (OR for higher physical activity: 0.20 (0.05 to 0.80) vs. 0.47 (0.11 to 1.16); OR for higher fitness: 0.19 (0.08 to 0.46) vs. 0.39 (0.19 to 0.76), in women and men, respectively).

Conclusions: Levels of physical activity and CRF were low in participants recruited to the Early ACTID Study. Although physical activity and CRF were not associated with glycaemic control, higher levels were associated with a lower prevalence of the metabolic syndrome. The protective effect of physical activity and CRF was stronger in women than men. The use of pedometers and diaries appears to be acceptable to adults with T2D who are attempting to increase their physical activity.

Acknowledgements

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Finally, I must thank Ian, for being so patient and tolerant, and my family and friends, who have all been somewhat neglected during the last few years, but whose love and support means so much to me.

Author's Declaration

I declare that the work in this dissertation was carried out in accordance with the Regulations of the University of Bristol. The work is original except where indicated by special reference in the text and no part of the dissertation has been submitted for any other degree.

Any views expressed in the report are those of the author and in no way represent those of the University of Bristol.

The report has not been presented to any other University for examination either in the United Kingdom or overseas.

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Appendices

Chapter 1. Introduction

The present chapter will briefly discuss the background to this PhD project. The current problem of type 2 diabetes and the potential influence of physical activity and cardiorespiratory fitness will be described. The chapter will close with an outline of how the study was first developed.

1.1. Background

Type 2 diabetes mellitus (T2D) has become a worldwide epidemic. The number of individuals with T2D has trebled in the last 30 years and there is no sign of this trend slowing down (Wild, Roglic, Green et al., 2004). Increasing rates of obesity and a move towards a more sedentary lifestyle are thought to be strongly associated with the rising prevalence of this condition.

The consequences of diabetes can be fatal. Fifty percent of people with the condition will die of cardiovascular disease (CVD) (WHO, 2004). Other risks include renal failure, blindness and lower limb amputation. Maintaining good glucose control and managing the clustering of cardiovascular risk factors typically found in people with T2D can help to reduce the risk of these complications (Stratton, Adler, Neil et al., 2000; UKPDS Group, 1998b) and is therefore the main aim of diabetes management.

Weight control, healthy eating and physical activity are considered the cornerstones of initial treatment for T2D (Mann, 2000). As the condition progresses, medication is usually prescribed in addition to lifestyle modification. The premise of advising people with T2D to engage in physical activity is based on strong epidemiological evidence from longitudinal studies that shows physical activity is inversely associated with the risk of developing T2D (Folsom, Kushi and Hong, 2000; Hu, Manson, Stampfer et al., 2001a; Hu, Sigal, Rich-Edwards et al., 1999; Manson, Nathan, Krolewski et al., 1992; Manson, Stampfer, Colditz et al., 1991; Weinstein, Sesso, Lee et al., 2004). A similar association has been reported for fitness (Lynch, Helmrich, Lakka et al., 1996; Sawada, Lee, Muto et al., 2003; Wei, Gibbons, Mitchell et al., 1999). Several large randomised controlled trials have shown that in people with impaired glucose tolerance, a pre-diabetic state, a combination of diet and physical activity can reduce the incidence of T2D by up to 58% (Diabetes Prevention Program Research, 2002; Pan, Li, Hu et al., 1997; Ramachandran, Snehalatha, Mary et al., 2006; Tuomilehto, Lindstrom, Eriksson et al., 2001). Additionally, two of these studies included a

medication only group, which was reported to have a higher incidence of T2D than the diet plus activity group (Diabetes Prevention Program Research, 2002; Ramachandran et al., 2006).

Prospective observational evidence shows that both physical activity (Batty, Shipley, Marmot et al., 2002; Gregg, Gerzoff, Caspersen et al., 2003; Hu, Stampfer, Solomon et al., 2001b; Hu, Jousilahti, Barengo et al., 2005; Hu, Qiao, Tuomilehto et al., 2004b; Tanasescu, Leitzmann, Rimm et al., 2003) and cardiorespiratory fitness (CRF) (Blair, Kohl, Paffenbarger et al., 1989; Church, Cheng, Earnest et al., 2004; Kohl, Gordon, Villegas et al., 1992; Wei, Gibbons, Kampert et al., 2000) can protect against cardiovascular and all-cause mortality in people with T2D. Furthermore, evidence from intervention studies shows that increased physical activity (Boulé, Haddad, Kenny et al., 2001; Di Loreto, Fanelli, Lucidi et al., 2003; Kirk, Mutrie, MacIntyre et al., 2004a; Snowling and Hopkins, 2006; Thomas, Elliott and Naughton, 2006) and CRF (Boulé, Kenny, Haddad et al., 2003) may produce improvements in glycaemic control and other metabolic and physiological outcomes.

Reported associations with health-related outcomes tend to be stronger for CRF than physical activity. This may be attributable to the differences in measurement error between the two exposures, as self-reported methods are typically used for the assessment of physical activity, while fitness will almost certainly always be measured directly, either by submaximal or maximal testing procedures. Measuring physical activity is challenging because of its complex nature. Self-reported measures tend to be crude and imprecise, and they are likely to weaken the strength of observed associations with health-related outcomes. The discrepancy in measurement precision between physical activity and CRF thus complicates the interpretation of results from epidemiological studies.

Objective measures of physical activity using sensitive instruments, such as accelerometers, provide more accurate data that can enhance our understanding of the association between different dimensions of physical activity and health. Unfortunately, very few data have been published that describe objectively-measured habitual physical activity levels in adults with T2D. Moreover, the independent cross-sectional associations of objectively-determined physical activity and CRF with glycaemic control and other physiological outcomes in T2D have not yet been established. It is therefore currently unknown whether physical activity or CRF is most important in T2D.

The accurate quantification of activity levels in this population is required in order to inform activity promotion and intervention strategies. Furthermore, determining the relative importance of physical

activity and CRF in relation to important health-related outcomes in people with T2D is required for the translation of research findings into clinical management, policy and practice recommendations.

1.2. Conception of the current project

In 2004 Diabetes UK, the largest diabetes research charity in the UK, agreed to fund six academics (Appendix 2) from the University of Bristol to conduct a randomised controlled trial (RCT) involving up to 750 adults with a recent diagnosis of T2D. The study, called Early ACTID, which stands for **Early ACT**ivity **I**n **D**iabetes, aimed to compare the effect of a one-year programme of *dietary advice plus home-based exercise* with *dietary advice only* and *usual care* on glycaemic control, blood pressure, blood plasma lipids and weight status. In addition, the grant included funding for a PhD project as part of the RCT. This thesis will focus on the PhD project, rather than the Early ACTID Study as a whole.

The broad aims of the PhD were to:

- develop intervention materials for the purpose of facilitating the initiation and maintenance of physical activity in *diet plus exercise* participants recruited to the Early ACTID Study,
- describe objectively measured physical activity in people participating in the Early ACTID Study,
- examine the six-month change in physical activity among participants in the Early ACTID Study,
- explore the use of pedometers and diaries to monitor daily physical activity over a six-month period among participants randomised to the *diet plus exercise* intervention of the Early ACTID Study,
- describe CRF levels in people participating in the Early ACTID Study,
- explore the independent associations of objectively measured physical activity and CRF with HbA_{1c} and the clustering of cardiovascular risk factors in people participating in the Early ACTID Study, and
- investigate whether there is an interaction effect between physical activity and CRF on HbA_{1c} and the clustering of cardiovascular risk factors in people with newly diagnosed T2D.

1.3. Contribution to the Early ACTID Study

This PhD project was closely linked to the Early ACTID RCT. The PhD researcher, herein described as the researcher, was solely responsible for developing the Early ACTID physical activity intervention programme. This involved: 1) developing a home-based activity programme suitable for adults with T2D, 2) developing and piloting participant materials that were based on physical activity behaviour change principles, 3) producing a detailed standard operating procedure for each participant visit that enabled the nurses to deliver the physical activity intervention and monitor adherence to the physical activity goals, and 4) providing training for the nurses and dietitians relating to the delivery of the physical activity intervention.

Once recruitment to the Early ACID study commenced in November 2005, the assessment of physical activity was the primary responsibility of the researcher. This involved developing measurement protocols, participant information sheets, initialising and downloading all activity monitors, and cleaning and analysing the physical activity data.

The measurement of cardiorespiratory fitness (CRF) was not part of the original Early ACTID Study proposal and the addition of this measure by the researcher thus added a unique aspect to the study. The researcher developed CRF measurement protocols, participant information sheets and data collection tools. The researcher administered 288 out of the 558 fitness tests (45%) that have been analysed for the purpose of this PhD thesis. The researcher also administered 51 12-month fitness tests; however, the data from these are not presented within this thesis.

A Gantt chart outlining the timescales for this PhD project can be seen in Appendix 3.

Chapter 2. Literature review

This chapter will start by providing an overview of the central themes of this thesis: type 2 diabetes (T2D), the clustering of risk factors associated with T2D, physical activity and cardiorespiratory fitness (CRF). Definitions, prevalence, health implications and measurement issues will be described. The subsequent sections will discuss some of the key observational and intervention studies that have examined associations between physical activity, CRF and T2D. Evidence for associations with glycaemic control, the clustering of risk factors and mortality in T2D will be presented. Although data from small experimental studies have contributed to the evidence base, this review will focus on the best available evidence, namely large epidemiological studies and well-designed intervention trials. The independent associations with physical activity will be reviewed first, followed by the associations with CRF. The relative importance of, and interaction between, these variables in relation to type 2 diabetes will then be examined. The final sections of this chapter will consider the evidence for promoting the adoption and maintenance of physical activity in people with T2D, focusing primarily on the components of previous intervention studies that have been successful at increasing participants' activity levels.

2.1. Literature search strategy

An extensive search of the literature pertaining to diabetes, physical activity and cardiorespiratory fitness was performed electronically through the Cochrane Central Register of Controlled Trials (CENTRAL), the Cochrane Database of Systematic Reviews (Cochrane Reviews), MEDLINE, EMBASE and PubMed. MEDLINE and EMBASE databases were combined through OVID to avoid repeating searches unnecessarily. In order to build on and update existing reviews, all databases were searched from January 1996 to August 2008, using the search strategy specified in Appendix 4. Searches were restricted to the titles of English language articles that were related to humans. In addition to the electronic searches, the reference lists of selected articles were checked for potential papers. The titles of articles were assessed for relevance. Where no clear decision could be made based on the title of the paper, the abstract and, when necessary, the full text was obtained for further evaluation. Articles that could not be obtained locally were ordered.

2.2. Central themes

2.2.1. Type 2 diabetes

Definition and prevalence

Diabetes mellitus is a chronic, progressive metabolic disorder characterised by elevated blood glucose levels. The disorder is rapidly increasing on a global scale. Worldwide prevalence is estimated at 171 million, which is predicted to double by 2030 (WHO, 2003). In the UK, 2.3 million adults are diagnosed with diabetes, and as many as 750,000 remain undiagnosed (The Information Centre for Health and Social Care).

Care of people with diabetes uses 5% of the total NHS budget and 10% of hospital inpatient resources (Wanless, 2002). People with diabetes are twice as likely to be admitted to hospital and stay twice as long. Once discharged, their care by community social services costs five times that of unaffected individuals (Bagust, Hopkinson, Maslove et al., 2002).

T2D is the most common clinical form of diabetes, accounting for approximately 90% of all cases in the UK. The proportion of people with this type of diabetes increases with age (Department of Health, 2003a), and it is strongly associated with obesity (Chan, Rimm, Colditz et al., 1994; Colditz, Willett, Rotnitzky et al., 1995), physical inactivity and family history of diabetes. Rates of T2D are much higher among ethnic minority communities, including those of South-Asian, African and African-Caribbean descent (WHO, 2003). Prevalence rates also appear to be higher in men than in women (Department of Health, 2003a; Wild et al., 2004). While the condition was previously seen only in middle-aged and older adults, T2D is being identified in younger age groups, including adolescents and children.

Diagnosis and measurement

The diagnosis of diabetes requires a random venous plasma glucose (RPG) test, a fasting venous plasma glucose (FPG) test, or an oral glucose tolerance test (OGTT) to be within the diabetic range shown in Table 2.1 (WHO, 1999). In the presence of diabetic symptoms (e.g. thirst, polyuria, unexplained weight loss, recurrent infections, neuropathic symptoms, vision changes, etc.) a single test is sufficient for diagnosis. However, in asymptomatic individuals, at least one additional abnormal plasma glucose concentration is required to confirm a clinical diagnosis (WHO, 1999).

Table 2.1. World Health Organization (WHO) diagnostic thresholds for venous plasma glucose (mmol/l)

	Random Plasma Glucose (RPG)	Fasting Plasma Glucose (FPG)	Oral Glucose Tolerance Test (OGTT)
Diabetes Mellitus	≥11.1	≥7.0	≥11.1
Impaired glucose tolerance (IGT)	N/A	<7.0	≥7.8 and <11.1
Impaired fasting glycaemia (IFG)	N/A	≥6.1 and <7.0	<7.8

(WHO, 2006)

Impaired glucose tolerance (IGT) and impaired fasting glycaemia (IFG) are additional categories of abnormal glucose tolerance which refer to metabolic states between normal glucose homeostasis and diabetes mellitus. Although they are not considered clinical entities, plasma glucose values within IGT and IFG ranges indicate that glucose is not being metabolised efficiently within the body. As such, the presence of IGT or IFG places individuals at high risk of developing diabetes and/or CVD (Alberti, 1996).

Following a diagnosis of diabetes, glycated haemoglobin (HbA_{1c}) can be measured to provide an objective indication of a patient's overall blood glucose control for the preceding six to eight weeks (Goldstein, Little, Wiedmeyer et al., 1986). Over the lifetime of a red blood cell (90 to 120 days), glucose binds to haemoglobin through a process called glycosylation. HbA_{1c} is a measure of the percentage of glucose-bound haemoglobin in the blood, and is considered one of the best measures of glycaemic control. The normal range found in healthy persons is between 3 and 5.9%. People with diabetes often have higher values, which can be categorised according to the ranges published by NICE (National Institute of Clinical Excellence (NICE), 2002), as outlined in Table 2.2. Higher $HbA1_c$ values are associated with increased risk of diabetes-related complications (UKPDS Group, 1998a).

Table 2.2. NICE guidelines for HbA_{1c} values (%) in people with diabetes

Control	HbA_{1c} (%)
Optimal	<6.0
Good	6.0 - 6.49
Target	6.5 - 7.49
Poor	≥ 7.5

(National Institute of Clinical Excellence (NICE), 2002)

Pathophysiology and aetiology

Although the exact pathogenesis and aetiology of T2D remains unclear, evidence from prospective cohort studies suggests that the main causes leading to its development are defects in insulin action and insulin

secretion (Saad, Knowler, Pettitt et al., 1991a). Insulin acts on cells in the liver, skeletal muscle and adipose tissue by binding to its specific receptor on the plasma membrane, triggering a series of intracellular protein phosphorylation steps that lead to glucose uptake. An inadequate effect of circulating insulin on glucose and fat metabolism is referred to as insulin resistance. Ultimately, insulin resistance leads to a reduced ability of insulin to promote glucose uptake in muscle and adipose cells, and to suppress liver glucose production after meals, which results in hyperglycaemia. Initially, the beta cells in the pancreas compensate for this by producing extra insulin (hyperinsulinaemia) in order to lower glucose levels. Eventually, due to partial failure of the pancreatic beta cells, insulin levels gradually decline, causing hyperglycaemia and glycated haemoglobin (HbA_{1c}) to rise steadily (Kahn, 2003). In some individuals, usually in the late stages of T2D, insulin production may even cease altogether.

Whereas insulin resistance, characterised by elevated levels of circulating insulin, is thought to be the primary defect that leads to impaired glucose tolerance, beta cell exhaustion is considered to play an essential role in the progression from impaired glucose tolerance to T2D (Saad et al., 1991a). Data from prospective observational studies have shown that normoglycaemic offspring of parents with diabetes have slower glucose removal rates and higher insulin levels in response to glucose tolerance tests when compared with offspring of parents without diabetes. Poor glucose removal rates and high serum insulin levels were found to independently increase the risk for developing diabetes among the offspring of diabetic parents (Ramachandran, Snehalatha, Premila et al., 1990; Warram, Martin, Krolewski et al., 1990). These data suggest impaired glucose tolerance is already present one or two decades prior to a diagnosis of T2D. This is accompanied by compensatory hyperinsulinaemia, suggesting that the primary defect is an inadequate action of insulin, rather than beta cell dysfunction.

The aetiology of T2D is a complex multifactorial process with both lifestyle and genetic origins. The aggregation found in non-diabetic families suggests insulin resistance is genetically determined (Sakul, Pratley, Cardon et al., 1997). However, the rapidly increasing prevalence of T2D over recent years indicates that non-genetic factors have significant influence in determining its onset. The most dramatic increases in T2D are occurring in societies in which there have been major changes in lifestyle. These changes include reductions in physical activity, increases in overweight and obesity, and a move towards diets that typically are energy-dense, high in total fat and saturated fatty acids and low in fibre. These lifestyle factors are thought to be key underpinnings in the aetiology of this chronic disease (King, Aubert and Herman, 1998).

Epidemiological data suggest that the main risk factors for T2D are age, obesity, centrally distributed excess adiposity, family history, physical inactivity and dietary factors (WHO, 2003). The presence of maternal diabetes, including gestational diabetes and intrauterine growth retardation, particularly when paired with later rapid catch-up growth, appears to also increase the risk of subsequent development of T2D (Dabelea, Hanson, Lindsay et al., 2000).

Consequences

In the UK, T2D is the leading cause of renal failure, one of the leading causes of blindness, and is the second leading cause of lower limb amputation (Department of Health, 2001). Furthermore, individuals with diabetes have up to a five fold increased risk of cardiovascular mortality (Valabhji and Elkeles, 2003). These microvascular and macrovascular complications, due to vessel damage, are independently and additively associated with long-term glycaemic and blood pressure control, with no evidence of any threshold of risk (Khaw, Wareham, Luben et al., 2001; Stratton, Cull, Adler et al., 2006; Stratton et al., 2000). In the UK Prospective Diabetes Study (UKPDS), patients with T2D were followed for ten years. Each 1% reduction in HbA_{1c} was associated with reductions in risk of 21% for any endpoint related to diabetes, 21% for deaths related to diabetes, 14% for myocardial infarction and 37% for microvascular complications. The lowest risk of complications was associated with HbA_{1c} values in the normal range (<6.0%) (Stratton et al., 2000).

Management

Blood glucose levels have been shown to increase progressively from diagnosis in people with T2D. Due to the increasing risk of morbidity and mortality associated with poor glycaemic control, the primary aim of diabetes management is to reduce hyperglycaemia. Weight reduction through energy restriction, exercise and oral hypoglycaemic medication remain the cornerstones of T2D management. The association between obesity and risk of developing T2D is well established. Furthermore, in people with T2D, obese individuals are at a greater risk of mortality than their non-obese counterparts. Weight loss in this patient population is strongly associated with improved insulin sensitivity, glycaemic control, blood pressure control and blood lipid profiles.

Exercise is encouraged as part of diabetes management, since evidence suggests that it may improve glycaemic control as well as risk factors for CVD. Physical activity is also associated with a lower risk of all-cause and cardiovascular mortality both in those with (Batty et al., 2002; Gregg et al., 2003; Hu et al.,

2001b; Hu et al., 2005; Hu et al., 2004b; Tanasescu et al., 2003)and without T2D (Löllgen, Böckenhoff and Knapp, 2009; Nocon, Hiemann, Muller-Riemenschneider et al., 2008) (insert references here to support this statement). When lifestyle modification fails to maintain sufficient glycaemic control, pharmacological treatment is prescribed, which can be effective in reducing glycaemia and thus in managing the disease. Several oral hypoglycaemic agents are now available, each differing in action and side-effects. The UKPDS examined the effects of different treatments for T2D, and found that diabetes control deteriorated over time, regardless of the type of pharmacological treatment used (UKPDS Group, 1998c). This was shown to be related to a gradual increase in insulin resistance combined with a decrease in insulin secretion. Much of the increased insulin resistance was due to weight gain, a side-effect of many oral treatment strategies in diabetes (LeRoith, 2002).

An ideal treatment for T2D would therefore improve glycaemic control and other risk factors for diabetes-related complications, including obesity, hypertension and hyperlipidaemia, without the presence of adverse side-effects. To date, no pharmacological treatment has satisfied these criteria. Physical activity, conversely, has few side-effects and has been shown to favourably influence risk factors in people with impaired glucose tolerance (IGT), a pre-diabetic condition. Thus, physical activity potentially represents the ideal first line treatment for T2D.

2.2.2. Clustering of risk factors associated with type 2 diabetes

Definition and prevalence

The 'Metabolic Syndrome' is a term used to describe a clustering of interrelated risk factors for CVD (Alberti, 2005). Typically, these risk factors include central obesity, hyperinsulinaemia, dyslipidaemia, hypertension and glucose intolerance (Alexander, Landsman, Teutsch et al., 2003).

The ultimate importance of recognising the metabolic syndrome is that it helps to identify individuals at high risk of both T2D and CVD. Until recently, however, there were no internationally agreed diagnostic criteria. Definitions have been produced by a number of groups, including the World Health Organization (WHO, 1999), The European Group for the Study of Insulin Resistance (EGIR) (Balkau and Charles, 1999), The National Cholesterol Education Program—Third Adult Treatment Panel (NCEP ATP III) (Grundy, Cleeman, Daniels et al., 2005), and, more recently, the International Diabetes Federation (IDF) (International Diabetes Federation, 2006). The definitions presented by these different groups have varied somewhat in specific elements or cut points, but in general they include a combination of common

cardiovascular risk factors. Table 2.3 shows the criteria proposed by these different organisations for the diagnosis of the metabolic syndrome. Only those criteria that may be appropriately applied to people with a diagnosis of diabetes are presented. Thus, the EGIR definition has been excluded because it was proposed for non-diabetic individuals only.

The existence of multiple definitions for the metabolic syndrome has caused confusion and has prevented the direct comparison of data between studies. The most recent definition, proposed by the IDF, was developed in an attempt to address both clinical and research needs by producing a universally accepted diagnostic tool suitable for worldwide use (International Diabetes Federation, 2006).

The prevalence of the metabolic syndrome inevitably depends on the definition and criteria used as different definitions are likely to identify different individuals (Cameron, Shaw and Zimmet, 2004). Generally, earlier definitions (NCEP ATP III) identify fewer individuals (~19%) than more recent definitions, such as the IDF (~31%) (Moebus, Hanisch, Aidelsburger et al., 2007). It is estimated that approximately 20-25% of the world's adult population have the metabolic syndrome (International Diabetes Federation, 2006). Data from European prospective cohort studies suggest the prevalence in men and women without diabetes is approximately 16% and 14%, respectively, when using a modified WHO definition (Hu et al., 2004b). In people with T2D, it is considered to be much more prevalent, with figures estimated to be as high at 80% (Ford, Giles and Dietz, 2002; Isomaa, Almgren, Tuomi et al., 2001).

Survey data obtained from a nationally representative sample of the US population between 1988 and 1994 found that the metabolic syndrome prevalence increased with age, rising from 7% among participants aged 20 years to approximately 43% among those in their 60s. Ethnicity and gender differences were also reported. In African Americans and Mexican Americans only, the prevalence was higher among women than men (Ford et al., 2002). In other ethnic groups there appears to be a trend for higher rates in men.

Prevalence is also thought to vary depending on the level of physical activity or fitness. Cross-sectional data show lower odds for the clustering of risk factors associated with the metabolic syndrome among increasing quartiles of physical activity and increasing tertiles of fitness (Carroll, Cooke and Butterly, 2000).

Table 2.3. Criteria proposed by different organisations for the clinical diagnosis of the metabolic syndrome

Organisation	Criteria						
	Essential component	Obesity/central adiposity	Blood pressure	Cholesterol	Insulin resistance	Glucose	Other
International Diabetes Federation (IDF) (Alberti, Zimmet, Shaw et al., 2005)	WC ≥94cm for Europid men and ≥80cm for Europid women and/or BMI ≥30, with ethnicity specific values for other groups PLUS at least two other factors	See essential component	≥130 systolic or ≥85mmHg diastolic, or treatment of previously diagnosed hypertension	1) TG 1.7mmol/L / 150mg/dL or specific treatment for this lipid abnormality 2) HDL Cholesterol ≤1.03mmol./L / 40mg/dL in men and ≤1.29mmol/L / 50mg/dL in women or specific treatment for this lipid abnormality	None	Fasting plasma glucose ≥5.6mmol/L or previously diagnosed T2D	None
NCEP ATP III [1] (Grundy et al., 2005)	Three out of five factors	WC ≥102 cm in men or ≥88 cm in women	≥130/85 mm Hg	1) TG ≥1.7mmol.L / 150mg/dL 2) HDL-C <1.04mmol/L / 40mg/dL in men or <1.3mmol/L / 50mg/dL in women	None	≥5.6mmol/L / 110mg/dL (includes diabetes)	None
World Health Organization (WHO) (WHO, 1999)	Glucose intolerance, IGT or diabetes and/or insulin resistance PLUS at least two other factors	Central obesity (males: waist to hip ration >0.90; females: waist to hip ratio >0.85) and/or BMI >30kg/m^2	≥140/90 mmHg	TG ≥1.7mmol/L / 150mg/dL and/or HDL cholesterol <0.9mmol/L / 35mg/dL for men; <1.0mmol/L / 39mg/dL for women	See essential component	None	Microalbuminuria (urinary albumin excretion rate ≥20g/min or albumin: creatinine ratio ≥30mg/g)

WC, waist circumference; BMI, body mass index; TG, triglycerides; HDL, high-density lipoprotein

[1] National Cholesterol Education Program (NCEP) Adult Treatment Panel (ATP) III

Diagnosis and measurement

The diagnosis of the metabolic syndrome depends on the definition, but will involve measuring the independent components, including obesity, waist circumference, blood pressure, fasting plasma glucose, triglycerides and plasma-lipoprotein cholesterol levels.

Pathophysiology and aetiology

While the pathogenesis of the metabolic syndrome and each of its components is complex and not well understood, central obesity and insulin resistance are considered to be important causative factors (Anderson, Critchley, Chan et al., 2001). While obesity contributes to hypertension, high serum cholesterol, low high-density lipoprotein (HDL) cholesterol and hyperglycaemia, central obesity, otherwise known as abdominal obesity, appears to have an even stronger association with metabolic risk factors (Balkau, Deanfield, Despres et al., 2007; Carr, Utzschneider, Hull et al., 2004; Grundy, Brewer, Cleeman et al., 2004), and in particular with insulin resistance (Despres, 2001). Several investigators have argued that insulin resistance is more important than obesity in the pathogenesis of the metabolic syndrome (Reaven, 1997). However, the close association between insulin resistance and obesity causes difficulties when attempting to identify their unique roles. The interaction of genetics, ethnicity, physical inactivity, ageing, a proinflammatory state and hormonal changes may also have a causal effect, although more research is required in order to determine the contributory role of each factor (Liese, Mayer-Davis and Haffner, 1998; Saad, Lillioja, Nyomba et al., 1991b).

Consequences

The most important dimension of the metabolic syndrome is its association with the risk of developing CVD. Since many people with the syndrome have some degree of insulin resistance, there is also an elevated risk of developing T2D. While each individual component of the metabolic syndrome is associated with increased CVD risk, it has been postulated by some that as a combination they become much more powerful (Hanefeld, Koehler, Gallo et al., 2007; Kaplan, 1989) in increasing risk of all cause and cardiovascular mortality (Benetos, Thomas, Pannier et al., 2008; Golden, Folsom, Coresh et al., 2002; Hu et al., 2004b). The issue relating to the potentially synergistic nature of the clustering of risk factors is contentious {Alexander, 2003 #638; McNeill, 2005 #759; Yarnell, 1998 #764 (include refs here to support this statement); however, the increased risk of CVD associated with the presence of the metabolic syndrome is well recognised.

In people without T2D, the metabolic syndrome is associated with a one and a half times greater risk of all cause mortality and a two-fold increased risk of cardiovascular mortality compared to those without the metabolic syndrome (Najarian, Sullivan, Kannel et al., 2006). In individuals with T2D, the coexistence of other metabolic syndrome factors denotes a much higher risk for the future development of CVD than those without additional factors (Alexander et al., 2003; Grundy et al., 2005; Najarian et al., 2006).

Management

The primary management for the metabolic syndrome is lifestyle modification that includes weight loss, changes in dietary composition and increased physical activity (Lindstrom, Louheranta, Mannelin et al., 2003). However, in individuals for whom lifestyle change is not sufficient, and who are considered to be at high risk for CVD, pharmacological therapy may be required. Since there is no specific treatment for the metabolic syndrome, it is necessary to manage the individual abnormal components of the syndrome in order to lower the overall CVD and diabetes risk.

2.2.3. Physical activity

Definitions and prevalence

Daily total energy expenditure (TEE) is comprised of three main components: basal metabolic rate (BMR), diet-induced thermogenesis and physical activity. The BMR represents the energy expended for normal cellular and organ function while at rest in a neutrally temperate environment, in the post-absorptive state. The BMR is primarily predicted by lean body mass and in sedentary populations is thought to account for approximately 60-75% of TEE {Levine, 2005 #766}. Although there is considerable variation between individuals in terms of TEE, reports suggest that, under respiratory chamber conditions, in which dietary intake and physical activity were both controlled, variations in BMR between individuals with similar body weights are limited and range between 7.9 and 12% of the population mean (Shetty, 2005).

Diet-induced thermogenesis relates to energy expended as a result of digestion, absorption and storage of food, and accounts for approximately 5%-10% of TEE (Donahoo, Levine and Melanson, 2004). Physical activity, which consists of both volitional and spontaneous activities, such as fidgeting, is the most variable component of TEE as the intensity and volume of activity varies considerably within and between persons. Consequently, physical activity can account for between 15% and 75% of daily total energy expenditure (Westerterp, 1998).

While physical activity refers to a behaviour and is defined by '...any force exerted by skeletal muscle that results in energy expenditure above resting level' (Caspersen, Powell and Christensen, 1985), exercise is a subset of physical activity and tends to be 'volitional, planned, structured, repetitive, and aimed at improvement or maintenance of any aspect of fitness or health' (Caspersen et al., 1985).

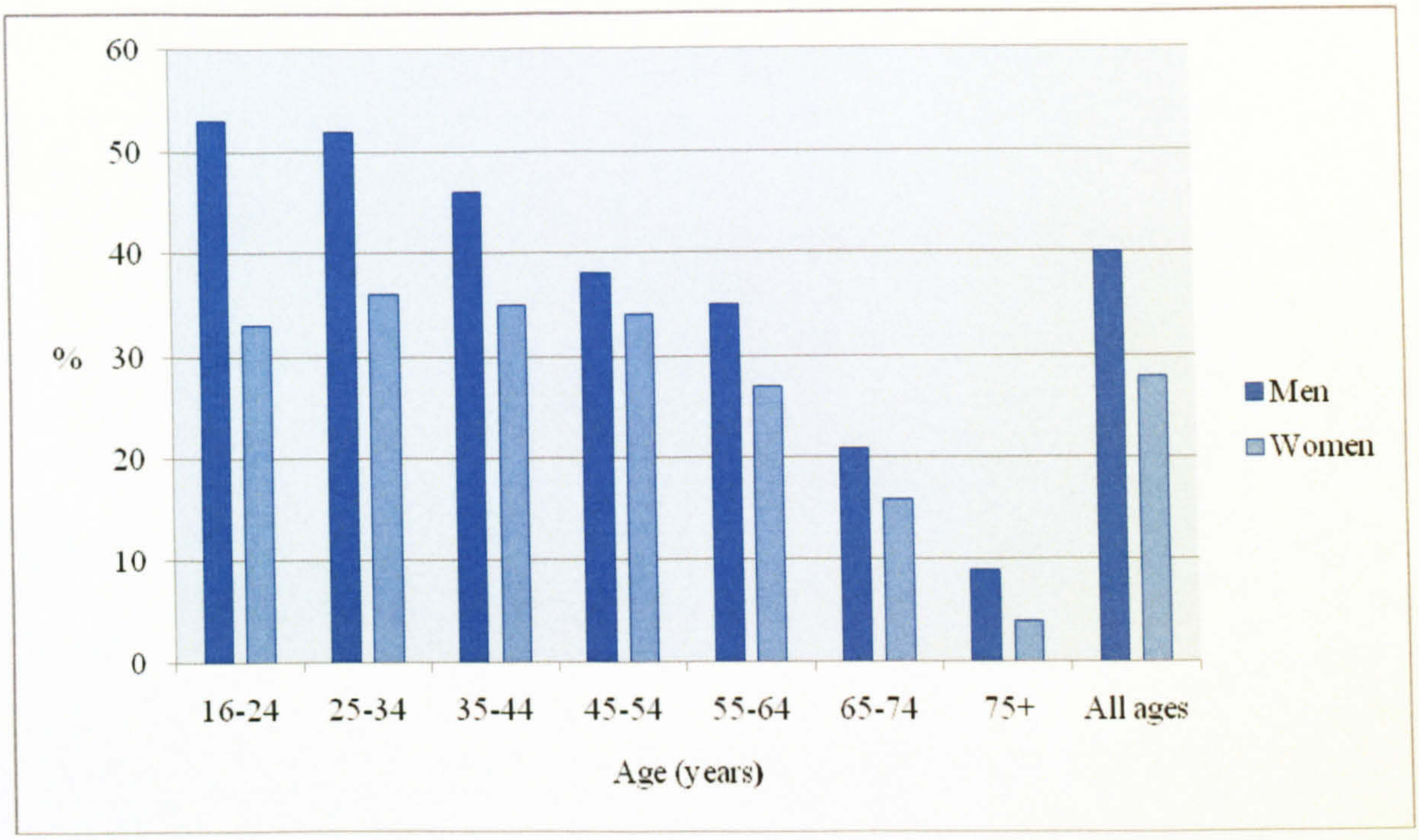
Over the past 20 or 30 years there has been a decrease in physical activity as part of daily life (Department for Transport, 2001). This decline has occurred at the same time as other societal changes, such as a reduction in manual jobs and developments in technology. Current national physical activity guidelines recommend that healthy adults should aim to be moderately active for at least 30 minutes on five or more days per week (Department of Health, 2004). Moderate intensity activities have an energy cost of between 3.5 and 7 kcal/min, or 3-6 METs (metabolic equivalent), and include brisk walking, cycling and other activities that increase the breathing and heart rate (Ainsworth and Youmans, 2002).

Figure 2.1 illustrates data collected from the 2005 Health Survey for England (HSE) (Department of Health, 2007), which show that just 35% of men and 24% of women reported achieving the recommended minimum level of physical activity. For both men and women, the proportion reaching recommended levels of activity was inversely associated with age. A particular concern raised by the survey's findings is that approximately one third of men and half of women reported doing less than 30 minutes of activity per week. These men and women can be classed as inactive or sedentary. Recently, The National Travel Survey (Department for Transport, 2006) found that 25% of all respondents reported taking walks of ≥20 minutes less than once per year or never.

Associations with health

A wealth of epidemiological evidence shows a clear dose-response relationship between physical activity and all-cause morbidity and mortality. In 2004, the Department of Health in England published the Chief Medical Officer's report 'At least five a week: Evidence on the impact of physical activity and its relationship to health' (Department of Health, 2004). The report highlighted the inverse relationship between physical activity and the development of diseases such as coronary heart disease, stroke, T2D, obesity and cancer. In addition, the evidence demonstrated that physical activity is associated with increased risk of hypertension, hyperlipidaemia, musculoskeletal disorders, impaired psychological well-being and mental illness. Low levels of physical activity have therefore become a major public health concern, particularly in western societies.

Figure 2.1. Percentage of adults achieving 30 minutes of moderate intensity physical activity on five or more days of the week by gender and age in England



(Department of Health, 2007)

The World Health Organization (WHO) reported that physical inactivity is one of the ten leading causes of death in developed countries, producing 1.9 million deaths worldwide per year (WHO, 2002). In terms of public health, the greatest reduction in risk can occur when people move from being sedentary to engaging in low to moderate levels of activity. Evidence shows that physical activity resulting in a weekly energy expenditure of between 500 and 1,000 kcals can reduce the risk of premature death by 20-30% (Lee and Skerrett, 2001).

A recent study calculated the costs of inactivity in the UK and reported that it was responsible for 3.1% of morbidity and mortality, and contributed over £1 billion per year to the direct health cost burden to the UK National Health Service (Allender, Foster, Scarborough et al., 2007). Other calculations of the cost of physical inactivity in England, which include the direct costs of health care and the indirect costs resulting from earnings lost due to inability to work and premature death, suggest the amount is £8.2 billion per year (Department of Culture Media and Sports Strategy Unit, 2002). Furthermore, this does not include the contribution of inactivity to obesity, which has been estimated to cost the NHS £0.5 billion annually, and the economy as a whole £2 billion.

Although the health benefits associated with a physically active life are well documented, occasionally physical activity can have adverse effects, such as injury. More serious, but fortunately rare, risks, including heart attack and sudden death, occur among predominantly sedentary individuals who occasionally perform vigorous exercise. Data from large-scale epidemiological studies show that the absolute risk of sudden death during a bout of exercise is extremely low (less than one death per 1.51 million exercise episodes in middle-aged men) and that habitual exercise diminishes this risk substantially (Albert, Mittleman, Chae et al., 2000; Thompson, Buchner, Pina et al., 2003; Thompson, Franklin, Balady et al., 2007; Vuori, 1995). As such, it is generally accepted that the potential health benefit resulting from engaging in regular, moderate-intensity activity, which is built up gradually, far outweighs any potential risks.

Measurement

The multidimensional nature of physical activity makes it a complex exposure to measure. As outlined in the WHO report (WHO, 2002), opportunities for activity exist in four major domains. These include work, transport, domestic duties, and leisure-time. This creates many challenges in terms of measurement, particularly when quantification of lifestyle or incidental activity is required. A variety of assessment methods have been used in physical activity research and can be broadly categorised as either subjective or objective (Lagerros and Lagiou, 2007). Subjective methods include questionnaires, recalls, logs and records, which all rely on self-report. Objective methods require the use of motion sensors, heart rate monitoring, indirect calorimetry, or the frequently considered gold standard method, doubly-labelled water. Each method has its own strengths and limitations, and the selection of a particular measure is determined by the scale and scope of the research study. Thus, choosing the appropriate method is a balance between validity, reliability and practicability (Lagerros and Lagiou, 2007).

Large scale epidemiologic studies typically use validated questionnaires due to the ease of distribution and the limited time and money that is required compared with more labour-intensive methods associated with objective assessments. In general, these questionnaires focus on either occupational or leisure-time activities, rather than assessing total physical activity, which also includes unstructured activities of daily living. As such, measures obtained through subjective methods are crude, imprecise and subject to error, and are likely to reduce the strength of observed relationships between physical activity and health, and to weaken the measured effect of interventions.

Objective measures of physical activity using sensitive instruments provide more accurate data that can enhance our understanding of the association between total physical activity and health. In particular, validated and reliable measures that provide information about the key dimensions of physical activity, including frequency, intensity and duration, can allow us to identify causal associations with health outcomes, which can lead to the formulation of clear policy and practice recommendations.

Accelerometers can provide such a measurement of physical activity as they are able to measure accelerations in up to three planes (vertical, mediolateral and antero-posterior) (Tudor-Locke and Myers, 2001a), therefore sensing all human motion while suppressing high accelerations that could only be attributable to non-human motion. Most accelerometers have a real-time internal clock that enables them to start recording data at a desired time and to sum data over a user-defined interval (epoch). The output generated is the summed amount and magnitude of accelerations for each epoch, displayed as counts, which can then be used to estimate the intensity of physical activity at a specific time.

Considerable research has been conducted to examine the validity and reliability of various accelerometers. One of the best monitors is the ActiGraph, which has been shown to strongly correlate with measured oxygen uptake under both laboratory (Brage, Wedderkopp, Franks et al., 2003; Freedson, Melanson and Sirard, 1998) and field (Brage et al., 2003; Hendelman, Miller, Baggett et al., 2000) conditions. Furthermore, in a comparison of four accelerometers across multiple trials, the ActiGraph monitor showed the least variability and the highest overall reliability when assessing physical activity in adults (Welk, Schaben and Morrow, 2004). In another recent study, the reliability between different ActiGraph monitors worn at the same time under free-living conditions was examined. Intraclass correlations were .97 for counts and ranged from .98 to .99 for minutes of different intensities (McClain, Sisson and Tudor-Locke, 2007). Intraclass correlations >.80 are generally considered highly reliable. The small and light design of the ActiGraph monitor means it is unobtrusive to wear, which, in addition to its other attributes, makes it one of the best assessment tools available for measuring free-living activity in adults.

2.2.4. Cardiorespiratory fitness

Definitions

Cardiorespiratory fitness (CRF), also referred to as cardiorespiratory endurance or aerobic capacity, is 'the ability of the circulatory and respiratory systems to supply oxygen during sustained physical activity' (Sigal, Kenny, Wasserman et al., 2004). CRF is an attained physiological state and the major component of

physical fitness that is inversely related to all-cause mortality. It is therefore considered an important health-related indicator. CRF is measured as VO_{2max}, which reflects the maximum rate that oxygen can be taken up and utilised by the body during exhaustive exercise. VO_{2max} is typically expressed as the total volume of oxygen used per kilogram of body weight per minute ($ml \cdot kg \cdot min^{-1}$), which enables individuals of different body masses to be compared.

Determinants

CRF varies considerably between untrained individuals. Inter-individual variation is attributable to a number of both non-modifiable and modifiable factors (American College of Sports Medicine, 1995). Non-modifiable factors include genetics, gender and age. Genetics are thought to be the most significant determinant, accounting for up to 50% of the variance between individuals (Bouchard, Daw, Rice et al., 1998; Bouchard, Dionne, Simoneau et al., 1992). Gender is also influential, with VO_{2max} values typically 15-25% lower in females than males. This difference has been ascribed to higher body fat percentages (Drinkwater, 1984), lower levels of haemoglobin in the blood (Cureton, Bishop, Hutchinson et al., 1986), and smaller hearts relative to body size in women compared with men (Mitchell, Tate, Raven et al., 1992). Evidence derived from cross-sectional and, more recently, longitudinal studies shows age to be inversely associated with CRF (Dehn and Bruce, 1972; Fleg, Morrell, Bos et al., 2005; Ogawa, Spina, Martin et al., 1992). This is illustrated in Table 2.4, which shows normative VO_{2max} data, divided into equal groups using quintiles for both men and women in different age categories (Heyward, 2006). Modifiable factors that influence CRF include body mass, body composition and exercise habits (Blair, Cheng and Scott Holder, 2001).

Table 2.4. Gender and age-specific VO_{2max} categories

Female (values in ml·kg·min^{-1})						
Age	**Very poor**	**Poor**	**Fair**	**Good**	**Excellent**	**Superior**
13-19	<25.0	25.0 - 30.9	31.0 - 34.9	35.0 - 38.9	39.0 - 41.9	>41.9
20-29	<23.6	23.6 - 28.9	29.0 - 32.9	33.0 - 36.9	37.0 - 41.0	>41.0
30-39	<22.8	22.8 - 26.9	27.0 - 31.4	31.5 - 35.6	35.7 - 40.0	>40.0
40-49	<21.0	21.0 - 24.4	24.5 - 28.9	29.0 - 32.8	32.9 - 36.9	>36.9
50-59	<20.2	20.2 - 22.7	22.8 - 26.9	27.0 - 31.4	31.5 - 35.7	>35.7
60+	<17.5	17.5 - 20.1	20.2 - 24.4	24.5 - 30.2	30.3 - 31.4	>31.4
Male (values in ml·kg·min^{-1})						
Age	**Very poor**	**Poor**	**Fair**	**Good**	**Excellent**	**Superior**
13-19	<35.0	35.0 - 38.3	38.4 - 45.1	45.2 - 50.9	51.0 - 55.9	>55.9
20-29	<33.0	33.0 - 36.4	36.5 - 42.4	42.5 - 46.4	46.5 - 52.4	>52.4
30-39	<31.5	31.5 - 35.4	35.5 - 40.9	41.0 - 44.9	45.0 - 49.4	>49.4
40-49	<30.2	30.2 - 33.5	33.6 - 38.9	39.0 - 43.7	43.8 - 48.0	>48.0
50-59	<26.1	26.1 - 30.9	31.0 - 35.7	35.8 - 40.9	41.0 - 45.3	>45.3
60+	<20.5	20.5 – 26.0	26.1 – 32.2	32.3 - 36.4	36.5 - 44.2	>44.2

(Heyward, 2006)

As well as inter-individual variation in untrained states, there is considerable variation between individuals in terms of adaptation or response to a programme of training. Data from 481 sedentary adults from 98 two-generation families participating in the HERITAGE Family Study showed considerable heterogeneity in the VO_{2max} response to a standardised 20-week training programme, with some individuals experiencing little or no gain, and others experiencing vast improvements in fitness. These data led the authors to suggest that 47% of the age and sex adjusted VO_{2max} response to the programme of exercise was hereditary (Bouchard, An, Rice et al., 1999). Subsequently, in a review of studies reporting inter-individual variation in responsiveness to standardised and controlled exercise-training programmes, Bouchard and Rankinen (2001) found that age, gender and ethnic origin only contributed to ~11% of the variance in response to regular physical activity, and that familial factors had a considerable influence in training responses.

Associations with health

Strong epidemiological evidence shows that, in both men and women, a strong inverse relationship exists between CRF and morbidity and mortality (Blair, Kampert, Kohl et al., 1996; Farrell, Cheng and Blair, 2004; Laukkanen, Lakka, Rauramaa et al., 2001; Myers, Prakash, Froelicher et al., 2002). Furthermore, higher levels of CRF have been shown to reduce the harmful effects of other risk factors for CVD and all-cause mortality, including smoking, high cholesterol and hypertension (Blair et al., 1996). For CRF, there appears to be a minimum threshold for protection against CVD and all-cause mortality, whereby the 25% of the population with the lowest levels of CRF are at particular risk (Williams, 2001). Improvements in

CRF have been shown to be associated with improvements in health (Blair, Kohl, Barlow et al., 1995; Erikssen, Liestøl, Bjørnholt et al., 1998).

Measurement

The gold-standard method of measuring cardiorespiratory fitness is directly measured maximal oxygen uptake (VO_{2max}), involving analysis of expired air samples collected while an individual performs exercise of progressing intensity. Although this method provides the most accurate determination of VO_{2max}, it requires sophisticated equipment, is costly, labour intensive and time-consuming, and is therefore used infrequently in field research. Estimating VO_{2max} using heart rate during maximal exercise testing is considered to be the next most accurate method. However, such testing requires individuals to exercise to the point of volitional fatigue, and is likely to pose risks for individuals with T2D, of whom many are obese, predominantly sedentary, and already experiencing diabetic complications.

In an attempt to overcome the limitations of maximal testing, submaximal tests have been developed, which allow the prediction of VO_{2max} without the cost, risk, time and effort on the part of the subject (Astrand and Ryhming, 1954; Kline, Porcari, Hintermeister et al., 1987). Many of these submaximal tests use the heart rate at different work loads to predict VO_{2max}, while others predict VO_{2max} from multiple regression equations that include various parameters, such as age, gender and weight. The central tenet of submaximal tests is that heart rate–a marker of relative effort–is linearly related to oxygen consumption. Submaximal tests have been developed for several modes of exercise, including walking, cycling and running. Walking tests are particularly useful however, since walking is an acceptable exercise mode for most adults, is used almost universally, and is suitable for testing various populations (Laukkanen, Oja, Ojala et al., 1992). Furthermore, submaximal tests based on walking are generally safe and are considered more feasible than tests based on running or jogging (Oja, Mänttäri, Pokki et al., 2001). For the purpose of testing on a large number of people, the test ought to be simple, reproductive and cost-effective.

2.2.5. The relationship between physical activity, cardiorespiratory fitness and health

It is acknowledged that both physical inactivity and low fitness can be considered as major and equally important risk factors for a wide range of chronic diseases in adulthood (Department of Health, 2004). Several large prospective observational studies provide strong evidence of an inverse dose-response gradient across both activity and fitness categories for morbidity from coronary heart disease (CHD), stroke, CVD and cancer. A similar association is also evident for CVD, cancer and all-cause mortality

(Blair et al., 2001). In a review of prospective observational studies reporting both physical activity and CRF in relation to health outcomes, Blair and colleagues (2001) identified just nine studies. When the inverse gradient between mortality and physical activity and CRF were compared, fitness appeared to be more strongly related with mortality than physical activity. However, it should be noted that none of the analyses reported from the studies included both activity and fitness in multivariable models. Furthermore, physical activity was assessed using self-report methods in the epidemiological studies reviewed. Fitness, on the other hand, is more precisely measured through maximal or submaximal exercise tests and the stronger association of mortality with CRF compared with physical activity could be attributed to the difference in measurement precision between the two exposures.

2.3. Physical activity and type 2 diabetes

2.3.1. Physical activity levels and type 2 diabetes

Observational evidence

Early cross-sectional observations of differences in the prevalence of T2D between rural and urban areas first indicated that there was an association with physical activity (Zimmet, Faaiuso, Ainuu et al., 1981). In the last 15 years, however, compelling data from large prospective studies have demonstrated that a sedentary lifestyle may play a role in the development of T2D. Helmrich and colleagues (1991) presented data from one of the first large-scale observational studies, involving 5,990 male University of Pennsylvania alumni, aged 39-68 years. In an average of 14 years follow-up, 202 cases of diabetes occurred. With each 500 kcal increase in reported weekly leisure-time physical activity energy expenditure, up to 3,500 kcal·week^{-1}, a 6% decrease in the age-adjusted risk for the development of diabetes was observed ($P<0.01$) (Helmrich et al., 1991). The protective effect of physical activity was most pronounced in individuals at highest risk of T2D, including those with a high body mass index (BMI), history of hypertension or a parental history of diabetes.

In a cohort of 21,271 US male physicians, reported participation in vigorous exercise five or more times per week was associated with a 42% reduction in the age-adjusted risk of T2D compared with those who exercised less than once per week (Manson et al., 1992). A dose-response relationship between increased exercise frequency and reduced risk for T2D was observed. Similar findings have been reported for

women. In 87,253 women participating in the US Nurses Health Study, the risk of developing T2D was 33% lower in participants who reported exercising vigorously at least once per week, compared with those who reported no weekly exercise (Manson et al., 1991). The reduction in risk for T2D was weakened after adjusting for BMI, but remained significant.

In a more recent analysis, where 534,928 female nurses were followed for eight years, a higher volume of self-reported physical activity attributable to walking was also associated with reduced relative risk for diabetes, and an inverse risk of developing the condition was reported across quintiles of reported physical activity (Hu et al., 1999). After adjusting for BMI, these relative risks corresponded to 1.00 (referent), 0.84, 0.87, 0.77 and 0.74, respectively. A study of combined lifestyle factors and risk of diabetes in this cohort identified that while overweight or obesity were the single most important predictors of diabetes, lack of exercise, a poor diet and current smoking were all associated with significantly increased risk, even after adjustment for BMI (Hu et al., 2001a). This study supports the notion that a significant proportion of cases of T2D could be prevented by the adoption of a healthier lifestyle.

European studies have reported similar results, although these studies have been limited to male participants. Swedish men reporting at least 40 minutes per week of moderate intensity activity had a 50% lower risk of diabetes than those who reported not participating in moderate activities or who participated for shorter durations (Lynch et al., 1996). The apparent protective effects of exercise were most pronounced in individuals at high risk for developing T2D, who had a 64% lower risk of developing the disorder compared with those who did not exercise to this level. In the UK, the British Regional Heart Study followed 5,159 men, aged 40 to 59 years, for an average of 16.8 years and found that there was a decreased incidence of diabetes with increasing levels of various recreational physical activity, ranging from regular walking and cycling to sporting or vigorous activities (Wannamethee, Shaper and Alberti, 2000).

The majority of the participants in these studies are Caucasian. However other ethnic groups have been observed, including African-American men and women (James, Jamjoum, Raghunathan et al., 1998), and Japanese-American men (Burchfiel, Sharp, Curb et al., 1995), in whom similar associations between physical inactivity and development of diabetes have been reported. Interestingly, one study reporting prospective observations among Hispanic and Asian women found no significant association between physical activity and diabetes risk (Hsia, Wu, Allen et al., 2005). Conversely, however, cross-sectional data from The San Luis Valley Diabetes Study, involving 219 Hispanic and non-Hispanic white men and

women with IGT, found that among all participants, higher self-reported physical activity levels were associated with lower mean insulin areas, independent of obesity, fat distribution and age ($P<0.001$) (Regensteiner, Shetterly, Mayer et al., 1995a).

In recent years, several cross sectional studies have aimed to quantify the number of people with T2D achieving recommended levels of physical activity. In a nationally representative survey of US adults, 39% of respondents with diabetes reported engaging in 150 minutes of physical activity a week compared to 58% of adults without diabetes (Morrato, Hill, Wyatt et al., 2007). Similarly, just 32% of 1,614 Canadian adults with T2D reported achieving the weekly recommendation of 150 minutes. The investigators found that a younger age, male gender, higher education, higher income and lower BMI were associated with achieving the recommended level of activity (Plotnikoff, Taylor, Wilson et al., 2006). An earlier study reported similar correlates of physical activity in 260 adults, aged 55 years and above, with T2D. Based on data from an interviewer-administered survey, Hays and Clark (1999) found that 55% of respondents reported doing zero minutes of weekly physical activity. While female respondents were more likely to report zero minutes of activity compared with men (58.3 vs. 47.4%), a younger age, higher level of education, fewer motivational barriers, and greater perceived health and performance expectations were correlated with higher levels of physical activity.

Over the past few years, increasing attention has been given to daily step recommendations. Although not evidence-based, the accumulation of 10,000 steps per day has been promoted as a useful activity target for the general population. The daily guideline of 30 minutes of at least moderate intensity activity translates to approximately 3,000-4,000 steps, providing they are 1) at least moderate intensity (i.e. 100 steps·minute^{-1}) (Tudor-Locke, Sisson, Collova et al., 2005), 2) accumulated in at least 10-minute bouts, and 3) taken over and above some minimal level of physical activity, below which individuals could be classified as sedentary (Tudor-Locke, Hatano, Pangrazi et al., 2008). At present, <5000 steps daily is generally considered sedentary. Thus, in addition to a minimal level of activity, accumulating 30 minutes of brisk walking a day is likely translate to 8000-9000 daily steps (Tudor-Locke et al., 2008).

Tudor-Locke and colleagues (2002a) conducted a cross-sectional study to assess pedometer-determined activity in 160 free-living men and women (mean age 52.4 ± 5.3 years and BMI 32.3 ± 5.7 kg/m^2) with T2D (mean duration 1.9 ± 5.3 years). Participants were instructed to wear the pedometer over three consecutive days, which included two week days and one weekend day. On average, participants accumulated 6662 ± 3077 steps per day, which are fewer steps compared to participants without diabetes

(7370 ± 3080) (Tudor-Locke, Ainsworth, Whitt et al., 2001). While daily steps did not differ significantly between men and women or by age, they were found to be inversely associated with BMI (r=-0.27, P<0.01). When analysed by BMI category, the greatest differences in daily steps were identified between normal weight participants and those with morbid obesity (F=2.96, P<0.05).

As well as differences in physical activity volume, differences in walking intensity have also been reported between people with and without T2D. Although a walking speed of 4.0 km/hr is widely accepted as moderately intense physical activity (Ainsworth, Haskell, Whitt et al., 2000), in a small study of 19 participants with T2D (mean age 54.1 ± 7.7 years and BMI 33.4 ± 4.9 kg/m^2), who had recently completed a self-paced walking programme, the median walking speed was 3.3 km/hr (Johnson, Tudor-Locke, McCargar et al., 2005). Despite accumulating an average of 9150 steps per day over the 3-day measurement period, the slow walking speed may mean that potential health benefits are not fully achieved. Unfortunately, since the relative intensity of the walking was not measured it is unknown whether the walking speed of 3.3km/hr was sufficient to reach the desirable intensity considered beneficial for health.

Prospective studies suggest that people who exercise have a 33-50% lower risk of developing T2D (Lynch et al., 1996; Manson et al., 1992) and the greater the volume of exercise, the lower the risk of developing the disease (Manson et al., 1992; Manson et al., 1991). Walking and cycling levels are also associated with reduced risk of T2D (Hu et al., 1999; Wannamethee et al., 2000). The reduction in risk can be seen across a range of physical activity patterns and intensities, although the precise type, intensity, frequency, duration or volume of activity needed to protect against T2D are unknown.

Cross-sectional data show that fewer adults with diabetes report achieving recommended levels of activity compared with healthy adults. Reported pedometer data provide further evidence that people with diabetes perform less activity than their healthy counterparts. Additionally, self-selected walking speed appears to be slower in those with diabetes compared to those without the condition.

Intervention evidence

In recent years, several clinical trials have assessed whether regular physical activity, with or without dietary intervention, can prevent the development of T2D in people with impaired glucose tolerance (IGT). The Da Qing Study (Pan et al., 1997) was the first RCT to evaluate a lifestyle intervention for the prevention of T2D. In this study 577 Chinese men and women (mean age 45 years) with IGT were

randomised by clinic into control conditions or one of three treatment groups, including diet only, exercise only, and diet plus exercise. The study was performed in community health clinic settings, using both group sessions and individual counselling to deliver the interventions. Participants in the exercise groups were encouraged to increase their leisure-time physical activity to 150 minutes per week. Activity was self-reported through forms and interviews. The cumulative incidence of diabetes at six years was 67.7% in controls compared with 43.8% in the diet group, 41.1% in the exercise group and 46% in the diet plus exercise group. The relative decrease in rate of development of diabetes in the treatment groups was similar when subjects were stratified as lean (BMI $<25kg/m^2$) or overweight (BMI $\geq 25kg/m^2$). After adjustment for baseline BMI and fasting glucose level, the diet, exercise, and diet plus exercise interventions were associated with 31%, 46% and 42% reductions in risk for developing diabetes.

In the Finnish Diabetes Prevention Study (Tuomilehto et al., 2001) a total of 522 overweight men and women with IGT were randomised to intervention or control conditions. Intervention participants received individualised counselling aimed at increasing physical activity, reducing weight, and modifying diet. Participants were also offered a supervised programme of circuit-type resistance exercises. Achievement of physical activity goals was self-reported in a questionnaire. During a mean follow up period of 3.2 years, the cumulative incidence of diabetes was 11% in the intervention group, compared with 23% in controls, which equates to a reduction in risk of 58%. When analysed by gender, the incidence of diabetes was 63% lower among men and 54% lower among women in the intervention group. Although the independent effect of diet and exercise were not examined, 86% of intervention participants and 71% of the control participants reported achieving the physical activity goals. It is therefore likely that the questionnaire used to assess attainment of the physical activity goals encouraged misclassification of activity levels.

The U.S. Diabetes Prevention Program (Diabetes Prevention Program Research, 2002) is the largest randomised clinical trial comparing diet plus exercise to treatment with Metformin, an oral antidiabetic agent, in 3,234 people (68% female; mean age 50.6 years; mean BMI 34.0) with IGT. Participants were randomised to placebo, Metformin or a lifestyle-modification programme. The lifestyle programme goals were a weight loss of at least 7% and at least 150 minutes of physical activity per week. Participants received sixteen individualised, one-to-one counselling sessions covering diet, exercise and behaviour modification designed to assist participants in achieving these goals. Subsequent monthly individual and group sessions were used to reinforce the behavioural changes. Self-reported levels of physical activity were assessed annually.

After an average follow-up of 2.8 years the lifestyle intervention was found to be significantly more effective than Metformin, with the incidence of T2D reduced by 58% in the lifestyle group and 31% in the Metformin group compared with placebo. By the end of the study, 38% of participants in the lifestyle group achieved a weight loss ≥7% and 58% reported achieving the physical activity goals. Treatment effects did not vary significantly by either race or gender, with the lifestyle intervention highly effective in all subgroups. The study was not designed to test the relative contribution of dietary changes, increased physical activity and weight loss to the reduction of risk of diabetes, and the independent effects of these components remain to be determined.

Physical activity is thought to reduce the risk for T2D by exerting favourable changes in insulin sensitivity and the metabolic syndrome, including reducing body weight, blood pressure, plasma levels of triglycerides, inflammation, fibrinolysis, and endothelial dysfunction, and increasing plasma levels of HDL-cholesterol (Hu, Lakka, Kilpelainen et al., 2007). An increasing body of evidence demonstrates that regular physical activity can improve insulin sensitivity and other components of the metabolic syndrome (Mayer-Davis, D'Agostino, Karter et al., 1998; Wannamethee et al., 2000), in addition to reducing the risk of developing the metabolic syndrome (Laaksonen, Lakka, Salonen et al., 2002).

Published data from the trials described above show that lifestyle interventions, including physical activity, dietary modification and weight loss, can reduce the risk of developing T2D by up to 58% among adults with impaired glucose tolerance. In addition to a reduced risk of T2D, favourable changes in several cardiovascular risk factors, such as a reduction in body weight, blood pressure, plasma levels of triglycerides and fasting and 2-hour glucose and HbA_{1c}, and an increase in HDL-cholesterol have been reported.

2.3.2. Physical activity and health-related outcomes in type 2 diabetes

Observational evidence

Observational evidence from several prospective studies shows that physical activity also offers protection in people with established T2D. In the Whitehall Study, 352 men were identified with T2D at baseline. At the 25-year follow-up, self-reported walking pace and leisure activity were inversely related to all-cause and CHD mortality after adjustment for a range of covariates. A linear trend was observed for both walking pace ($P<0.05$) and leisure activity ($P<0.02$) across activity levels, and the association was steeper in individuals with T2D, when compared with normoglycaemics (Batty et al., 2002).

Data from a National Health Interview survey of 2,896 adults with diabetes were examined to determine the association between time spent walking and the risk of all-cause mortality (Gregg et al., 2003). Compared with inactive individuals, those who reported spending at least 2 hrs·wk^{-1} walking had a 39% lower all-cause mortality rate and a 34% lower rate of CVD mortality. This difference persisted after correcting for sex, age, BMI, and smoking. Walking for 3 to 4 hrs·wk^{-1} was associated with the lowest rates of mortality, as was walking that involved moderate increases in heart and breathing rates.

Prospective observational evidence also exists for the joint associations of physical activity and conventional cardiovascular risk factors with total and cardiovascular mortality among patients with diabetes (Hu, Jousilahti, Antikainen et al., 2007; Hu et al., 2005). A total of 3,708 Finnish adults, aged 25-74 years, with T2D were followed for a mean duration of 18.7 years. A moderate or high level of self-reported physical activity, including occupational, commuting and leisure-time activity, was associated with a reduced risk of total and CVD mortality. Obesity, high blood pressure and current smoking were independently associated with an increased risk of total and CVD mortality. A high serum total cholesterol level was associated with an increased risk of CVD mortality only. Interestingly, the protective effect of physical activity was evident regardless of BMI, blood pressure, cholesterol and smoking status.

Other prospective studies have reported similar findings among men and women with T2D, and have provided further evidence that physical activity is inversely associated with incidence of cardiovascular events and mortality from all causes and CVD in a dose-response manner (Hu et al., 2001b; Hu, Lindstrom, Valle et al., 2004a; Tanasescu et al., 2003).

Intervention evidence

Over the past decade there has been increased interested in the use of exercise as a means of managing glycaemic control in T2D. Until recently, all intervention trials of exercise in people with established T2D had fewer than 25 patients, most were not randomised, used poorly validated measures of glycaemic control and employed different exercise regimens. A meta-analysis of these studies was first published in 2001 (Boulé et al., 2001). Included studies were restricted to randomised and non-randomised controlled clinical trials that lasted at least eight weeks, in which it was possible to quantify the type, frequency, duration and intensity of the exercise intervention. A total of 14 trials were eventually analysed, describing interventions (mean duration 18 ± 15 weeks) in 504 people with T2D (mean age 55 ± 7 years, duration of T2D 4.3 ± 4.6 years). The exercise interventions typically prescribed three sessions per week, each lasting

a mean of 53 ± 17 minutes, including ten minutes of warm-up and cool-down. The intensity of the aerobic exercise was moderate and generally consisted of walking or cycling. Progressive resistance training was used in two intervention studies. Eleven of 14 trials were randomised, but when the results were compared in sensitivity analyses, no significant differences were detected between the randomised and non-randomised controlled trials. The quality of the trials was assessed as moderate to low.

Post intervention HbA_{1c} was significantly lower in exercise than control groups (7.65% vs. 8.31%), with a weighted mean difference of -0.66% (95% confidence interval (CI) -0.98 to -0.20, P<0.001). Differences in HbA_{1c} between exercise and control groups were similar after both aerobic training and resistance training interventions. The change in HbA_{1c} reported in this meta-analysis is a clinically significant reduction that would be expected to reduce the risk of diabetic complications (Stratton et al., 2000). No post-intervention statistical differences were found in body mass between the two groups, suggesting that the reduction in HbA_{1c} was independent of change in BMI.

Although this meta-analysis has attempted to quantify the effect of exercise on HbA_{1c} in people with T2D, the reported reduction in HbA_{1c} should be interpreted with caution as some non-randomised trials were included, and also some trials in which a programme of exercise plus diet was compared with a standard control programme that did not include diet (Agurs-Collins, Kumanyika, Ten Have et al., 1997; Fujii, Okuno, Okada et al., 1982; Vanninen, Uusitupa, Siitonen et al., 1992). Thus, it is not possible to determine the effects of exercise per se, and the inclusion of these studies could have led to an over-estimation of the magnitude of HbA_{1c} response to an exercise intervention. Furthermore, it should be noted that the majority of the included studies lasted less than three months, and generalising these findings to longer durations is therefore not appropriate.

A further meta-analysis was published in 2006, which aimed to explore the independent effect of exercise on a range of health outcomes in people with T2D (Thomas et al., 2006). Fourteen randomised controlled trials met the inclusion criteria. Trials ranged from eight weeks to 12 months in duration and involved 377 participants. The number of participants in a single study ranged from 16 to 49. The reviewed exercise interventions typically involved three sessions per week with exercise occurring on non-consecutive days. Both resistance and aerobic exercise was included. Compared with control conditions, HbA_{1c} was significantly lower after an exercise intervention (-0.6%, 95% CI -.09 to -0.3, P<0.05), with subgroup analyses revealing greater reductions with interventions less than three months' duration. Additionally, the meta-analysis found a reduction in visceral adipose tissue (-45.5cm^2, 95% CI -63.8 to -27.3) and a decrease

in plasma triglycerides (-0.25 mmol/L, 95% CI -0.48 to -0.02). No significant difference was found between groups in body mass, plasma cholesterol, blood pressure, VO_{2max} or quality of life.

An additional meta-analysis, published in the same year, examined the effects of different modes of exercise training on glucose control and risk factors for complications in adults with T2D (Snowling and Hopkins, 2006). The meta-analysis included 27 controlled intervention studies, lasting between five and 104 weeks. A total of 1,003 participants (mean age 55 ± 7 years) with T2D were included. An overall reduction in HbA_{1c} of 0.8% (95% CI -1.3 to -0.2) was reported for training that lasted at least 12 weeks. Although the effects of covariates were generally trivial or unclear, the authors noted small additional benefits of exercise on glucose control with increased disease severity. Differences among the effects of aerobic, resistance, and combined training on HbA_{1c} were trivial.

A summary of the best available intervention evidence for the effects of exercise on glycaemic control is presented in Table 2.5. The largest exercise intervention in people with T2D was conducted by Di Loreto and colleagues (2003). The RCT was designed to validate a counselling strategy that could be used by physicians to promote physical activity to patients. A total of 340 patients (mean age 62 years) were randomised to either the usual care or intervention group. Usual care participants received 30 minutes of standard counselling for diet and physical activity and a 15-minute outpatient appointment once every three months. In addition to this, intervention participants received 30 minutes of structured physical activity counselling, and monthly telephone calls to discuss perceived barriers. Physical activity was assessed using questionnaires. At the 2-year follow-up, participants in the intervention arm reported significantly more activity than those in the control arm ($P<0.001$). Furthermore, HbA_{1c} was significantly lower in the counselling group compared to the control group (7.0 ± 0.1% vs. 7.6 ± 0.1%, $P<0.001$), and this was positively related to the reported increase of energy expenditure through voluntary physical activity ($r=.63$).

Subsequently, the investigators published post-hoc analyses of the long-term effects of different amounts of reported increased energy expenditure of 179 adults (mean age 62 years) randomised to the physical activity counselling intervention (Di Loreto, Fanelli, Lucidi et al., 2005). Based on the 2-year change in reported physical activity, participants were divided into six groups, corresponding to the following increments in METs hour per week ($METs \cdot hr^{-1} \cdot wk^{-1}$): group 0 (no activity, n=28), group 1-10 (6.8 ± 0.3, n=27), group 11-20 (17.1 ± 0.4, n=31), group 21-30 (27.0 ± 0.5, n=27), group 31-40 (37.5 ± 0.5, n=32), and group >40 (58.3 ± 1.8, n=34). After two years, no parameter changed in group 0 or in group 1-10; in

Table 2.5. Key intervention studies reporting HbA_{1c} response to programmes of physical activity in people with type 2 diabetes

Author (Date)	Study type	Population	Intervention	Follow-up	Measurement	Results and comments
Boulé et al. (2001)	Meta-analysis including 12 RCTs & 2 CCTs	504 men and women (55.0y)	12 aerobic training; 2 resistance	15 weeks (mean)	Self-report	HbA_{1c} was lower in exercise compared with control groups, with a weighted mean difference, -0.66% (95% CI -0.98 to -0.20, P<0.01).
Di Loreto et al. (2003)	RCT	340 adults (161 men; 179 women) (62.0y)	Exercise counselling	24 months	PA questionnaire	At baseline HbA_{1c} was similar between usual care (7.7%) and intervention (7.6%) participants. At follow-up, the counselling group reported significant more PA than control group (P<0.01). HbA_{1c} was decreased by a greater extent in the intervention group (-0.6%) compared with the control group (-0.1%). HbA_{1c} was inversely related to reported PA (r=0.63, P<0.001)
Kirk et al. (2004a)	RCT	70 adults (35 men; 35 women) (57.6y)	Exercise counselling	6 months 12 months	ActiGraph accelerometers; 7-day PA recall	Baseline HbA_{1c} values were 8.8% and 8.3% for control and intervention groups, respectively. At 6 months, the intervention group had significantly increased reported & objectively measured PA, which was maintained at 12 months (P<0.01). Controls had significantly reduced PA (P=0.03). At 6 months there were significant between-group differences in changed HbA_{1c} (control, 0.37%; intervention, -0.31%, P<0.05). At 12 months, mean difference between groups in change in HbA_{1c} was not significant.
Bjørgaas et al (2005)	RCT	29 men (57.4y)	Supervised exercise 1.5h·wk^{-1} + pedometer for self-monitoring	12 weeks	Pedometer + PA diary VO_{2max} during submaximal treadmill test	At baseline, PA correlated with VO_{2max} (r=.43, P-0.02). At follow-up, HbA_{1c} was decreased by a greater extent in the intervention group (-0.4%) compared with the control group (-0.06%). Change in pedometer activity was correlated with HbA_{1c} (r=.84, P<0.01). Participants with high exercise attendance had a greater reduction in HbA_{1c} (-0.71%) compared with low attendance (-0.02%,) (P=0.03). A greater reduction in HbA_{1c} after exercise was observed with baseline values above the median compared with values below. Relationship between HbA_{1c} and VO_{2max} not reported
Thomas et al (2006)	Meta-analysis including 14 RCTs	361 men and women (mean age 55-65y)	6 aerobic training; 3 resistance; 4 mixed aerobic and resistance; 1 Qi Gong	8 weeks – 12 months		HbA_{1c} was lower in exercise compared with control groups, with a weighted mean difference, -0.6% (95% CI -0.9 to -0.3%, P<0.01). For studies less than three months, the decrease was -0.8% (95% CI -1.2 to -0.4, P<0.05).

RCT, randomised controlled trial; CCT, controlled trial; T2D, type 2 diabetes mellitus; PA, physical activity; r, correlation coefficient

groups 11-20, 21-30, 31-40, and >40, HbA_{1c}, blood pressure, total serum cholesterol, triglycerides, and estimated percent of 10-year coronary heart disease risk improved (P<0.05). In group 21-30, 31-40, and >40, body weight, waist circumference, heart rate, fasting plasma glucose, serum low-density lipoprotein (LDL) and HDL-cholesterol also improved (P<0.05). METs·hr^{-1}·wk^{-1} correlated positively with changes of HDL-cholesterol and inversely with those of other parameters (P < 0.001). The authors concluded that reported energy expenditure >10 METs·hr^{-1}·wk^{-1} obtained through aerobic leisure-time physical activity is sufficient to elicit improvements in health-related outcomes in T2D, however a greater range of improvements are achieved with energy expenditure >20 METs·hr^{-1}·wk^{-1}.

In another physical activity counselling intervention (Kirk et al., 2004a), 70 participants (mean age, 57.6 ± 7.9 years; women, 50%) with T2D were randomised to either receive standard written exercise information or physical activity counselling involving two 30-minute discussions with a trained researcher. Physical activity was objectively measured using an ActiGraph accelerometer and blood samples were analysed to determine HbA_{1c}. At the six-month follow-up, the counselling group had significantly increased physical activity (P<0.01), which was maintained through to 12 months. Follow-up physical activity levels in the control group were significantly lower compared with baseline (P<0.03). The mean difference between groups in HbA_{1c} change from baseline to six months was -0.7% (95% CI -1.23 to -0.07). Furthermore, between group differences were also reported for a range of cardiovascular risk factors, including systolic blood pressure, fibrinogen and total cholesterol, with the exercise group faring more favourably (P<0.05). This is the only identified study that used accelerometers to assess physical activity in people with T2D.

The studies described above support the use of exercise for the purpose of improving glycaemic control. Current evidence suggests that HbA_{1c} can be reduced by approximately 0.6% in response to a programme of exercise. The magnitude of this reduction is clinically significant. Limited evidence suggests exercise may also be useful for improving other risk factors in people with T2D, although there is a need for larger efficacy studies to establish the magnitude of resulting improvements.

2.3.3. Summary

It is well established that the incidence of T2D is higher in less active populations. Over recent years, data from large-scale prospective studies provide compelling evidence for the independent role of physical activity in the prevention of T2D. The benefits of physical activity are apparent in both men and women, and in younger and older individuals, even after controlling for various potential confounders, such as

gender, age and BMI. Despite methodological limitations, such as reliance on self-reported physical activity levels, several large intervention studies have since added to this body of evidence, showing clearly that increasing levels of physical activity, together with the adoption of a healthy diet, can prevent, or at least delay the development of T2D in people who are at high risk of the disorder. Moreover, evidence shows that a healthy lifestyle in people with IGT can offer greater protection against T2D than oral hypoglycaemic agents alone.

Cross-sectional evidence shows that people with T2D report being less active than the general population, and chose to perform activities at a lower intensity than those without the condition. Furthermore, fewer people with T2D report meeting current physical activity guidelines compared to people without diabetes.

In people with T2D, prospective observational evidence shows a general dose-response relationship between physical activity level and protection against diabetes-related morbidity and mortality in both men and women. Moreover, this association between physical activity and cardiovascular and all-cause mortality appears to be even stronger among people with T2D compared with the general population (Batty et al., 2002). Current intervention evidence suggests that a range of physical activities and exercise intensities can produce a clinically and statistically significant improvement in glycaemic control in people with T2D. These improvements are independent of weight loss, and have been reported after relatively short time-periods, such as a few months. Generally, shorter intervention periods have produced greater reductions in glycaemia compared with longer interventions.

Although data suggest that physical activity is associated with improved glycaemic control, various methodological limitations require the data to be interpreted with caution. The use of subjective questionnaire-based methods for assessing physical activity is one such limitation. Self-reported physical activity is known to be imprecise and leads to misclassification. Consequently, the true association between physical activity and health-related outcomes is likely to be underestimated, making it difficult to interpret the findings or quantify the dose-response relationship. The absence of a controlled diet or the measurement of diet in some of these published trials could have resulted in the strength of the association being overestimated. Finally, the lack of post-intervention follow-up in most of the short-term studies means it is not possible to determine whether the more marked improvements in glycaemic control are maintained long-term.

There is a lack of data on objectively-measured physical activity levels in people with T2D. Accurate quantification of habitual activity in this population, and the association with health-related outcomes, is necessary to inform future interventions and policy and practice recommendations.

2.4. Cardiorespiratory fitness and type 2 diabetes

2.4.1. Fitness levels and type 2 diabetes

Observational evidence

Evidence for the association between objectively measured CRF at baseline and subsequent diabetes risk is based on a just a few large prospective studies (Bjornholt, Erikssen, Liestol et al., 2001; Carnethon, Gidding, Nehgme et al., 2003; Eriksson and Lindgarde, 1996; Lynch et al., 1996; Sawada et al., 2003; Wei et al., 1999). One of the first of these to assess CRF by exercise testing involved 897 middle-aged Finnish men who were followed for four years (Lynch et al., 1996). CRF was measured with ventilatory gas analysis during a maximal bicycle ergometry test. A total of 202 T2D cases were diagnosed from 2-hour postload glucose concentrations. After adjusting for several confounders, odds ratios for incident diabetes in the first, second, third and fourth quartile of CRF, were 1.00 (referent), 0.77, 0.26, and 0.15, respectively.

In the Aerobics Center Longitudinal Study (ACLS) 8,633 US men, aged 30-79 years, were followed for an average of six years. Compared with those in the high-CRF group (most fit 40%), as determined by a maximal treadmill test, participants in the lowest-CRF group (least fit 20%) at baseline had a 1.9-fold risk for impaired fasting glucose (IFG), and a 3.7-fold risk for T2D (Wei et al., 1999). The inverse gradient occurred in men with high or normal BMI, those with or without a family history of diabetes, and those with normal or impaired fasting glucose (IFG) at baseline.

More recently, a 14-year prospective study of 4,747 Japanese men, aged 20-40 years, has been published (Sawada et al., 2003), which investigated the association between VO_{2max}, predicted from a cycle ergometer test, and the incidence of T2D. During the 14-year follow-up, 280 cases of T2D were identified based on three diagnostic parameters, including glucose tolerance testing, fasting blood glucose testing, or the reporting of hypoglycaemic therapy. The adjusted relative risks (RRs) of developing diabetes across increasing quartiles of fitness were 1.00 (referent), 0.78, 0.63, and 0.56.

The Coronary Artery Risk Development in Young Adults (CARDIA) study of 2,478 men and women in the United States, aged 18 to 30 years, assessed whether low fitness predicted the development of T2D or the metabolic syndrome over 15 years of follow-up (Carnethon et al., 2003). Additionally, change in fitness over a seven-year period was examined in relation to risk. After multivariate adjustments, participants with low fitness (bottom 20%) were approximately twice as likely to develop T2D or the metabolic syndrome compared to those with high fitness (top 40%). Improving fitness over seven years was associated with a 60% reduction in subsequent risk for T2D and 50% reduction for the metabolic syndrome.

Until recently there was a dearth of data on fitness and risk of T2D among women; however a 17-year observational prospective study of 6,249 women, aged 20-79 years, has been published within the past year (Sui, Hooker, Lee et al., 2008). All women were free of CVD, cancer and diabetes at baseline. CRF was measured using a maximal treadmill exercise test. Women were categorised into tertile groups based on their baseline fitness. Compared with the least fit group, BMI-adjusted hazard ratio (HR) was 0.86 (95% CI 0.59 to 1.25) for the moderately fit group and 0.61 (95% CI 0.38 to 0.96) for the most fit group. The authors found that low CRF and high BMI were independently associated with the incidence of T2D.

On average, individuals with T2D have VO_{2max} values that are 20-25% below that reported in age- and sex-matched sedentary individuals without T2D (Regensteiner, Sippel, McFarling et al., 1995b). While it is thought that the reduced fitness is at least partly due to an excess fat mass in this population, differences in the region of 20% have also been found in comparison to healthy controls that were matched for body weight (Regensteiner, Bauer, Reusch et al., 1998).

Fitness has a large genetic component with predispositions to muscle fibre type and lung volume, and, when combined with the genetic component of insulin resistance and diabetes, it results in an inherited impaired exercise capacity of first degree relatives of diabetic individuals (Thamer, Stumvoll, Niess et al., 2003). A normoglycaemic population, half without a family history and half with a first degree relative with T2D were compared in terms of their habitual activity, VO_{2max} and glucose control. Despite comparable levels of habitual activity, the relatives were found to have significantly reduced VO_{2max} and elevated blood glucose levels after adjustment for age and body weight. The use of questionnaires to assess habitual activity, and higher rates of obesity in relatives, means that some of this discrepancy may be explained by recall bias in the reporting of activity.

No intervention studies were located that investigated VO_{2max} response to a programme of exercise in relation to the development of T2D.

Until recently, data reporting the association between cardiorespiratory fitness and the risk of developing T2D were derived mainly from men. Associations appear to be similar to those found in studies of physical activity, however associations for fitness appear to be stronger. Larger magnitudes of association with fitness could be due to the use of more precise measures for this exposure. Furthermore, biological factors can influence both CRF and health (Blair et al., 2001).

2.4.2. Cardiorespiratory fitness and health-related outcomes in type 2 diabetes

Observational evidence

Several longitudinal data sets provide evidence showing that CRF predicts cardiac mortality in people with T2D. Wei et al. (2000) examined the association of low CRF and physical inactivity with mortality in 1,263 men (mean age 50 years) with T2D from the ACLS cohort. CRF was measured by a maximal treadmill test. Men were then categorised as either unfit or fit according to whether their fitness value was below or above the median. Participants were also categorised according to self-reported activity within the previous three months. Active men were those reporting at least one bout of walking, jogging or aerobic exercise, while those reporting no such activity were classed as inactive. Between 1970 and 1994, 180 deaths occurred. After adjusting for confounders, the RR of mortality was 2.1 and 1.7 with low levels of objectively determined fitness and reported physical activity, respectively.

An updated study from the same research team has been published subsequently, with almost twice as many men (Church et al., 2004). Since obesity is strongly associated with T2D, and is thought to increase risk of mortality among people with the disorder, data from 2,196 men (mean age 49.3 years) with T2D were analysed to quantify the relation of fitness to mortality, adjusting for BMI. After adjustment for confounders, the RR across quartiles of CRF was 1.00 (referent), 0.63, 0.36, and 0.22. The men were also grouped according to BMI-defined categories, including normal weight, overweight and obese. A steep inverse association was seen across quartiles of fitness within each BMI category, suggesting that the inverse relationship between CRF and mortality is independent of BMI.

Evidence also exists that shows improvements in CRF over time are associated with lower subsequent mortality rates, and deterioration in CRF is associated with higher subsequent mortality rates (Blair et al., 1995; Erikssen et al., 1998).

Kohl and colleagues (1992) analysed prospective data from 8,715 men (mean age 42 years) in order to determine the association between baseline CRF and all-cause mortality across a range of blood glucose levels. Included men underwent maximal-exercise treadmill testing at baseline and were followed for an average of 8.2 years. The investigators found that age-adjusted death rates increased with higher levels of fasting blood glucose. However, fit men were found to have lower age-adjusted all-cause mortality rates than their less fit counterparts, regardless of glycaemic status. This association was also found in men with T2D. Multivariate analyses that controlled for risk factors of mortality, including age, resting systolic blood pressure, serum cholesterol, BMI, family history of heart disease, follow-up interval and smoking habit, showed a higher risk of death due to all causes for unfit compared with fit men. Multivariate relative risks (RR) of death associated with low fitness, compared with high fitness, in the three glycaemic status groups were: 1.38 (95% CI 1.09-1.74) for fasting plasma blood glucose (FPG) <6.4 mmol/l, 1.61 (95% CI 0.91 to 2.86) for FPG 6.4-7.8 mmol/l, and 1.92 (95% CI 0.75 to 4.90) for FPG ≥7.8 mmol/l or with T2D. These data suggest that even when glucose control is poor, fitness may still protect against mortality.

In a recent cross-sectional study, Kadoglou and colleagues (2008) examined the interaction between cardiorespiratory capacity and cardiovascular risk factors in 40 men and 52 women with T2D. Cardiorespiratory capacity was assessed during a symptom-limited incremental ergometer exercise test, with continuous gas exchange measurement. All patients were overweight or obese (BMI >25), with poor glycemic control (HbA_{1c} >7%), but free from overt diabetic vascular complications. Based on the median VO_{2peak} value, participants were placed into a low fitness (n=46) or moderate fitness group (n=46). After adjustment for age and gender, exercise capacity correlated with systolic (r=-.349) and diastolic blood pressure (r=-.441), waist circumference (r=-.345), total cholesterol (r=-0.348), HDL-cholesterol (r=.362) and homeostasis model assessment (HOMA-IR) (r=-.467) (P<0.05). Compared to the low fit group, patients with moderate fitness showed significantly higher levels of HDL-cholesterol and lower blood pressure, waist circumference and HOMA-IR (P<0.05). These data indicate that low cardiorespiratory fitness seems to be independently associated with most traditional cardiovascular risk factors in patients with T2D.

Overall, findings of an inverse association for CRF and mortality in men and women with T2D are generally consistent and indicate that protection against mortality may be provided by moderate to high levels of fitness, irrespective of body weight and glycaemic control. Since CRF appears to offer significant protection against mortality in diabetes, analyses have been performed in an attempt to quantify the volume of physical activity associated with moderate fitness (Stofan, DiPietro, Davis et al., 1998). A total of 17,000 mainly non-diabetic participants from the ACLS completed physical activity diaries in addition to undergoing maximal exercise testing. The mean time per week spent exercising was 130 minutes for men and 148 minutes for women who were classified as moderately fit (21st to 60th percentile for age) and whose only reported exercise was walking. Comparisons between people with diabetes and non-clinical groups have not been located.

Intervention evidence

As mentioned previously, cardiorespiratory fitness is determined both by genetic factors and by habitual physical activity. Improvements in CRF in response to identical structured aerobic exercise programmes can vary considerably between individuals (Bouchard et al., 1999), and until recently the degree to which VO_{2max} could be improved in response to increased exercise in people with T2D was unknown. In order to address this, a meta-analysis quantifying the effect of structured, supervised exercise training on CRF in men and women with T2D was performed by Boulé and colleagues (2003). Randomised controlled trials (RCTs) evaluating the effect of interventions lasting at least eight weeks on CRF (as determined directly or derived from an equation after maximal testing) were included. A total of seven studies that presented data for nine training programmes were analysed, representing 266 adults (mean age 55.7 years, mean duration of T2D 4.1 years), of whom 40% were female. The quality of the trials was assessed as moderate to low. Physical activity programmes lasted for a mean duration of 20 weeks, and typically consisted of three bouts of walking or cycling per week, with each bout lasting approximately 40 minutes. Exercise intensities ranged from 50% to 75% of VO_{2max}, while exercise volume ranged from 8.75 to 24.75 METs·hr^{-1}·wk^{-1}.

Mean baseline VO_{2max} was 22.4 ml·kg·min^{-1} with no significant difference between groups. Overall, there was an 11.8% increase in VO_{2max} in the exercising groups and a 1.0% decrease in VO_{2max} in the control groups (post intervention standardised mean difference=0.53; 95% CI 0.18 to 0.88, P=0.003). Compared with no difference at baseline, post intervention HbA_{1c} values were lower in the exercise groups than control groups (weighted mean difference=-.71%; 95% CI -1.1 to -0.32, P=0.0004). Post-intervention

standardised mean difference in VO_{2max} was significantly associated with weighted mean difference in HbA_{1c} (r=-.72, P=0.04).

Meta-regression analyses were performed to detect associations between the standardised mean difference in VO_{2max} and specific training characteristics. Only the association between mean difference in VO_{2max} and exercise intensity reached borderline significance (r=.28, P=0.08). No significant associations were found with exercise volume per week (MET·hrs·wk^{-1}) (r=-.03, P=0.94), total exercise volume (MET·hrs) (r=-.35, P=0.35), bout frequency (r=-.10, P=0.79), bout duration in minutes (r=-.28, P=0.15), or duration of programme (r=-.38, P=0.32).

Eight out of the nine comparisons included in the meta-analyses reported HbA_{1c} values (n=250). The exercise characteristic showing the strongest correlation with the weighted mean difference in HbA_{1c} between the exercise and control groups was relative exercise intensity (r=-.91, P=0.002). There was no significant correlation between difference in HbA_{1c} and absolute intensity (r=-.33, P=0.42), exercise volume per week (MET·hrs·wk^{-1}) (r=-.46, P=0.26), or total volume (MET·hrs) (r=-.12, P=0.8).

Despite low CRF levels at baseline, the meta-analysis by Boulé and colleagues demonstrates that aerobic fitness can be improved in people with T2D to an extent that is comparable with reported improvements in older healthy individuals (Nelson, Rejeski, Blair et al., 2007). The meta-analysis showed a strong and significant association between mean change in VO_{2max} and HbA_{1c} response to a programme of exercise, and reported that these changes tended to be correlated with intensity of exercise. However, these results should be interpreted with caution, since many of the included studies had small sample sizes and variable results (Dunstan, Daly, Owen et al., 2002; Tessier, Menard, Fulop et al., 2000; Vanninen et al., 1992). It is also likely that the analysis was biased by the inclusion of one study (Mourier, Gautier, De Kerviler et al., 1997) that featured unequivocally high-intensity exercise (75% of VO_{2max}), resulting in the greatest increase of VO_{2max} (40.9%) and the greatest reduction in HbA_{1c} (1.5%). Furthermore this study included the youngest participants, which might have influenced their response to a training programme. This intensity is likely to be difficult to sustain in people with T2D, many of whom are obese and predominantly sedentary.

2.4.3. Summary

Longitudinal evidence from just a few large cohort studies suggests there is a strong, independent inverse association between objectively measured CRF and risk of developing T2D, which remains after adjusting

for potentially confounding variables, including age, BMI, family history of diabetes, and diagnosis of IGT at baseline. No intervention evidence was located that examined the relationship between CRF and development of T2D.

In people with T2D, longitudinal data show CRF is inversely correlated with all-cause and cardiac mortality, irrespective of body weight, and glycaemic control. Evidence also shows that improvement in fitness is associated with reduced subsequent risk of mortality. Equally, reduced fitness related to increased risk.

Limited data from intervention studies demonstrate that aerobic fitness can be improved in people with T2D, and that increased VO_{2max}, produced by a programme of relatively vigorous, structured aerobic exercise training, is strongly associated with clinically significant improvements in HbA_{1c}. There is now a need to assess the efficacy of home-based, moderate-intensity exercise for improving HbA_{1c} and other important health outcomes in diabetes. Moreover, examining the cross-sectional association between objectively-measured habitual physical activity and CRF may allow effective targeting of intervention programmes.

2.5. Relationships between physical activity, cardiorespiratory fitness and health-related outcomes in diabetes

A number of epidemiological studies have examined the association between both physical activity and cardiorespiratory fitness with health outcomes related to diabetes. Both exposures are inversely related to the development of T2D and also premature mortality among those with T2D. As mentioned in previous sections, prospective observational data suggest that health is more strongly related to fitness than physical activity (Blair et al., 2001; Blair and Church, 2003; Laaksonen et al., 2002; Lakka, Laaksonen, Lakka et al., 2003; Oja, 2001; Wei et al., 2000). However, compared to CRF, which is measured objectively and reliably, physical activity measures are usually based on self-reported methods, which are typically crude and imprecise. Imprecise measures will undoubtedly lead to misclassification of the exposure, and this in turn will weaken the observed association with outcomes, and thus underestimate the strength of the true relationships.

In order to compare and explore the independent and combined associations of fitness and physical activity with health outcomes, comparable measures of the exposures are required. Objective, valid and reliable methods of measuring physical activity are therefore necessary. Since few objectively-determined physical activity and CRF data exist in adults with T2D, this section will highlight the findings of studies in non-diabetic populations that may have implications for those with the condition.

In a cross-sectional study of 589 Danish children (mean age 9.6 years), Brage and colleagues (2004) examined the relationship between the metabolic syndrome and objectively measured physical activity. A potential modification effect of CRF on this relationship was also assessed. Physical activity was measured using accelerometry and fitness was measured using a maximal cycle test. Metabolic risk, computed based on blood pressure, degree of adiposity and fasting levels of insulin, glucose, triglycerides and HDL-cholesterol, was inversely related to physical activity (P=0.008). However, the strength of this association was weakened after adjustment for fitness. Examination of the interaction between physical activity and fitness showed that the association between activity and metabolic risk was greatest in children with lower cardiorespiratory fitness levels.

Franks and colleagues (2004) explored similar associations in adults. Presented data were based on 874 healthy participants from the Ely Study, which is a prospective population-based cohort study of the aetiology and pathogenesis of T2D and related metabolic disorders. Physical activity was measured objectively by individually calibrated heart rate monitoring over a 4-day period, while VO_{2max} was predicted from a submaximal exercise test with direct assessment of oxygen uptake. A metabolic syndrome score was computed by summing standardised values for obesity, hypertension, hyperglycaemia, insulin resistance, hypertriglyceridaemia, and the inverse level of HDL-cholesterol. After adjusting for confounders and bivariate measurement error, there was a strong and significant inverse relationship between physical activity energy expenditure (PAEE) and metabolic syndrome score (P=0.004). The relationship between VO_{2max} and metabolic syndrome score was much weaker and reached only borderline significance (P=0.06). However, when the data were stratified above and below the median for VO_{2max} and by quartile for PAEE, the authors found that VO_{2max} significantly modified the association between the metabolic syndrome score and PAEE, even after adjustment for age, sex and bivariate error correction (P=0.036). The inverse association between physical activity and metabolic syndrome risk was present only in those who were below the median in CRF.

The same study group subsequently described the prospective association over a 5.6 year period between objectively-measured PAEE and aerobic fitness with the metabolic syndrome (Ekelund, Brage, Franks et al., 2005). Data were presented for 605 middle-aged men and women who were free of the metabolic syndrome at baseline. The group reported that PAEE predicts progression towards the metabolic syndrome in a dose-dependent manner and that this association is not explained by obesity, level of aerobic fitness, or other potential confounding factors. After adjusting for physical activity level, the investigators did not observe an association between aerobic CRF and the metabolic syndrome.

Conversely, previous prospective studies have found CRF to be independently predictive of the metabolic syndrome (Laaksonen et al., 2002), although adjustment for physical activity level was not performed.

In order to separate the effects of fitness and physical activity energy expenditure in the aetiology of the metabolic cardiovascular syndrome, Wareham et al (1998) estimated 4-day energy expenditure and CRF in a cross-sectional population-based study of 162 adults aged 30-40 years. Individuals were categorised as having the metabolic syndrome if at least one of four risk factors were present, including hypertension, hypertriacylglycerolaemia, low HDL-cholesterol and glucose intolerance. Heart rate (HR) monitoring with individual calibration was used to measure mean resting energy expenditure and total energy expenditure, which has been validated previously. VO_{2max} was assessed during submaximal testing on a cycle ergometer. Twelve men (16.4%) and 16 women (18.0%) were defined as having one or more features of the metabolic cardiovascular syndrome. The univariate odds ratio for each increasing quartile of physical activity level (PAL) was 0.64 (95% CI 0.43 to -0.94) and 0.49 (95% CI 0.32 to 0.74) for VO_{2max}, suggesting that the association with the metabolic syndrome was stronger for fitness than for PAL. Conversely, after adjustment for obesity, sex, and correction for exposure measurement error, the odds ratio per quartile for PAL was 0.32 (95% CI 0.13 to 0.83) and 0.44 (95% CI 0.24 to 0.78) for VO_{2max}. These findings suggest that PAL is a major determinant of the metabolic syndrome, although the small sample size and cross-sectional nature of these data requires caution to be applied when interpreting the results.

2.5.1. Summary

Few data have been published comparing the influence of physical activity and CRF on glycaemic control, cardiovascular risk factors or mortality in people with T2D. Analyses that have attempted this comparison suggest the relationship is stronger for CRF than physical activity. However, these analyses are based on

self-reported physical activity data and thus, it is not surprising that a stronger relationship has been reported with CRF, particularly since CRF is often used as an objective surrogate measure of physical activity due to the well-recognised limitations of self-reported behaviour. Since CRF is a function of both physical activity and non-modifiable genetic factors, without accurate knowledge of activity level, it is impossible to compare the independent associations of these exposures with health-related outcomes in diabetes. Finally, it is unknown whether physical activity and CRF interact in a unique and independent manner with metabolic and cardiovascular risk factors in people with T2D. Unfortunately, data on these objectively-determined variables are currently unavailable in this clinical population.

2.6. Promoting physical activity in people with type 2 diabetes

2.6.1. Interventions and strategies to increase physical activity in people with type 2 diabetes

It is well acknowledged that participation in regular physical activity offers many benefits to health and wellbeing, yet achieving greater participation in physical activity remains a major challenge, and the successful adoption and maintenance of physical activity is notoriously difficult to achieve, particularly in people with diabetes (Ford and Herman, 1995; Hays and Clark, 1999; Krug, Haire-Joshu and Heady, 1991).

A number of theoretical models have attempted to explain physical activity behaviour, and understanding the factors that influence this behaviour is imperative for the development of effective interventions (Kirk and De Feo, 2007). Although consensus regarding the best theoretical model for understanding exercise behaviour has not yet been achieved, one theory that has been particularly useful is the transtheoretical model (Prochaska and Marcus, 1994). While the model was initially applied to areas such as smoking cessation and dietary modification, a meta-analysis reviewing its application in the area of exercise behaviour provides strong support for its use in facilitating adoption and maintenance of physical activity (Marshall and Biddle, 2001).

The transtheoretical model, otherwise referred to as the stages of change model, postulates that there are five different cognitive stages regarding readiness to changing a behaviour. These stages include precontemplation, contemplation, preparation, action and maintenance. The implication of this model is

that interventions designed to facilitate adoption and maintenance of a particular behaviour should be tailored to the stage of readiness of the individual concerned.

Three factors are hypothesized to mediate the change process. These include self-efficacy for change, the decisional balance of perceived advantages and disadvantages of change, and the strategies and techniques (the processes of change) used to modify behaviour. The importance of self-efficacy for initiating and maintaining a pattern of regular physical activity derives from social–cognitive theories of behaviour (Bandura, 1977). Self-efficacy refers to a person's perceived confidence in their ability to successfully perform a particular behaviour, and consistent evidence demonstrates that exercise self-efficacy is positively related with stage of change and level of physical activity (Marshall and Biddle, 2001).

Behaviour change is assumed to involve a systematic evaluation of the potential gains (pros) and losses (cons) associated with the new behaviour (Marcus, Rakowski and Rossi, 1992), whereby perceived pros increase and perceived cons decrease with progression through the stages. Thus, an individual is more likely to be active if their perceived pros outweigh their perceived cons of the behaviour.

Ten processes of change that describe the strategies and techniques people use to modify their behaviour have been proposed. Five of these are said to be experiential and include consciousness-raising, dramatic relief, environmental re-evaluation, self-re-evaluation and social liberation. The other five processes are described as behavioural and include counter-conditioning, helping relationships, reinforcement management, self-liberation and stimulus control (Prochaska, Velicer, DiClemente et al., 1988).

Large-scale, randomised intervention trials involving sedentary adults have shown that the promotion of cognitive and behavioural intervention strategies can result in significantly increased levels of physical activity. Cognitive and behavioural strategies that are most strongly associated with physical activity include goal setting, self-monitoring, feedback, support, evaluation of progress and identification of barriers for relapse prevention (Calfas, Sallis, Oldenburg et al., 1997; Writing Group for the Activity Counseling Trial Research Group, 2001).

A systematic review of physical activity interventions confirmed the importance of cognitive and behavioural strategies in terms of facilitating physical activity adoption and maintenance at an individual level (Kahn, Ramsey, Brownson et al., 2002).

Recently, guidelines for conducting physical activity consultations in people with insulin resistance and T2D have been published (Kirk and De Feo, 2007; Kirk, Barnett and Mutrie, 2007). Physical activity

consultation is primarily based on the transtheoretical model and employs key strategies and techniques shown to promote and maintain behaviour change that are tailored to each particular stage. Effective promotion of physical activity for up to two years has been demonstrated with this type of intervention and has been shown to also improve health-related outcomes in adults with T2D (Di Loreto et al., 2003; Kirk, Mutrie, MacIntyre et al., 2003; Kirk et al., 2004a; Kirk, Mutrie, MacIntyre et al., 2004b). Interventions employing similar strategies have also been effective in increasing exercise among people at high risk of developing T2D (Diabetes Prevention Program Research Group, 2002).

Interventions based on physical activity consultation typically involve a person-centred one-to-one discussion on at least one occasion. The consultation approach is semi-structured to ensure that the key elements of the transtheoretical model are covered and that the intervention is tailored to the individual's stage of change and particular needs. It is agreed that stage-specific strategies should be employed in order to facilitate physical activity behaviour change. Table 2.6 presents these strategies. It is also recommended that an individual's self-efficacy should be assessed and explored. The agreement of short-term, intermediate-term and long-term physical activity goals is a key component of the consultation, and these goals should be specific, measurable, acceptable and realistic.

A small pilot study in adults with T2D indicates that feedback may further facilitate adoption and maintenance of physical activity (Paschali, Goodrick, Kalantzi-Azizi et al., 2005). Of 26 adults (mean age 48.1 years) receiving physical activity counselling for three months, half were randomised to receive accelerometer feedback on their physical activity while the other half were blind to accelerometer data. Those without feedback received counselling based on their self-reported activity data. The non-feedback group were found to have increased activity six weeks post-randomisation but reverted back to baseline levels at three months. The feedback group, on the other hand, increased activity at three months, however this change was only borderline significant ($P<0.08$), which could have been attributable to the small sample size.

Table 2.6. Stages of exercise behaviour change and appropriate strategies for facilitating change, adapted from Kirk and De Feo (2006)

Stage	Definition	Appropriate strategy
Precontemplation	Inactive and not thinking about becoming more active within the next 6 months	• Information/advice on risks of inactivity and benefits of activity
Contemplation	Inactive and thinking about becoming more active within the next 6 months	• Decisional balance (weight up pros and cons of becoming active) • Discuss and overcome barriers
Preparation	Doing some physical activity and preparing to do more within the next month	• Develop realistic activity goals • Establish support
Action	Doing enough physical activity but have done so for less than six months	• Reinforce successful attempts • Re-emphasise experience benefits • Overcome experience barriers
Maintenance	Has made physical activity a habit for six months or longer	• Relapse prevention • Alternative activities

While theoretical models have proved essential for the development of interventions that aim to increase physical activity, the type of physical activity promoted is also an important consideration. Evidence appears to support the use of lifestyle activity, and in particular walking, compared to more structured programmes of exercise (Dishman, 1994; Dunn, Marcus, Kampert et al., 1999). Walking is the most prevalent form of activity, and its widespread use lies in the fact that it requires no special skills or facilities and is achievable by most people. Indeed, walking accounts for a substantial proportion of the energy expenditure associated with physical activity in sedentary individuals and is often reported as their preferred type of activity (Crespo, Keteyian, Heath et al., 1996).

2.6.2. Pedometers

In recent years, pedometers have become a popular tool for use in physical activity intervention programmes, since they are relatively inexpensive, easy to use, and have been reported to be motivational to those using them while attempting to adopt a more active lifestyle (Heesch, Dinger, McClary et al., 2005). Most electronic pedometers consist of a horizontal spring-suspended lever arm that moves with the vertical acceleration of the hips during ambulation (Tudor-Locke, Williams, Reis et al., 2004). These instruments display the number of steps taken on a digital screen and a reset button allows the user to sum steps over any desired duration.

Bravata et al. (2007) performed a systematic review to evaluate the association of pedometer use with physical activity and health outcomes among outpatient adults. Twenty-six studies (eight RCTs, 18 observational), with a total of 2,767 participants, were included in the review. The mean intervention duration was 18 weeks. Overall, pedometer users increased physical activity by 26.9% over baseline. Intervention participants from the RCTs increased their physical activity by 2,491 steps per day (95% CI 1098 to 3885, P<0.0001) compared with controls, while pedometer users from observational studies increased daily steps by 2,183 (95% CI 1571 to 2796, P<0.001).

The authors of the systematic review also used meta-regression to evaluate participant and intervention characteristics that predicted improvements in physical activity among pedometer users. No specific participant characteristics (gender, age, ethnicity, BMI or baseline physical activity) were found to significantly predict increases in physical activity. Of the intervention characteristics, Bravata and colleagues found that having step goals and diaries were key characteristics associated with increased physical activity (P=0.001). Participants without a step goal did not increase physical activity. Interestingly, no significant increase in activity was found among participants in the three studies that did not include step diaries. Five of the included studies evaluated participants' adherence with keeping step diaries, and a mean of 83% ± 20% was reported. Rather surprisingly, the authors did not find that physical activity counselling increased daily steps. However, this could be attributed to the heterogeneity of the counselling provided and is not consistent with the findings of studies in people with T2D that compared activity counselling with no counselling, without the use of pedometers (Di Loreto et al., 2003; Kirk et al., 2004b). Furthermore, some of the included studies that provided counselling may not have reported doing so.

In 30 participants with T2D, Araiza and colleagues (2006) conducted a six-week randomised controlled trial. Intervention participants (n=15) were instructed to walk at least 10,000 steps per day on five or more days per week for six weeks, while control participants were asked to maintain baseline physical activity levels for the duration of the trial. The intervention group increased steps by 69% during the intervention, from 7220 ± 2792 to 10410 ± 4162 (P=0.002), while there was no change in the control group. Although this study is small, it shows that a simple intervention of providing a pedometer and step target promotes significant increases in walking over at least six weeks.

Gleeson-Kreig (2006) found that monitoring activity using daily records may also be useful for promoting self-efficacy, which has been shown to predict physical activity levels. A total of 58 adults (40-65 years)

with T2D were randomly assigned to control conditions or six weeks of pedometer use and self-monitoring using daily activity records. Although follow-up physical activity levels were not different between the two groups, those using records reported significantly increased self-efficacy compared to controls, which was maintained throughout the six-week intervention period. The authors concluded that daily physical activity records were acceptable to participants.

In a small eight-week pilot study of the First Step Program, a lifestyle physical activity intervention, Tudor-Locke et al. demonstrated the potential effectiveness of a pedometer-based intervention for promoting physical activity in nine people with T2D (mean age 53 years; BMI 32.9 kg/m^2). As well as significant increases in walking compared with baseline (mean difference 34.3$min \cdot day^{-1}$), participants described pedometers as a "novel and highly useful motivator" (Tudor-Locke, Myers, Bell et al., 2002b).

Two years later, the findings from the full 16-week intervention study were published (Tudor-Locke, Bassett, Swartz et al., 2004). Out of 60 participants initially randomised in the study, a total of 47 overweight and obese sedentary individuals (mean age 52.7 years; BMI 33.3 kg/m^2) completed baseline and post-intervention measures. Participants were randomly assigned to either the control group or the First Step Program, which is based on theoretical principles of self-efficacy and social support, and includes goal-setting, self-monitoring and feedback. The intervention programme consisted of weekly group meetings during the initial four weeks, where participants were provided with pedometers and the programme manual containing goal-setting and problem-solving exercises, as well as calendars for self-monitoring daily steps. Participants were requested to monitor steps for the remaining 12 weeks of the intervention.

Among intervention participants, compliance with record keeping was 100% at the start of the 16 weeks, 88% after the first four weeks, and 58% during the last four weeks. First Step Program participants increased their physical activity by 3370 ± 3780 steps per day (<0.001), which was a significant improvement compared to control participants -675 ± 2574 (P<0.0001). Participants were also followed up at 24 weeks, eight weeks after contact had discontinued. Although daily steps remained higher in the intervention group compared with the control group (7924 ± 3308 vs. 6557 ± 2742), the difference was non-significant.

These findings suggest that relatively short-term programmes of pedometer use and self-monitoring can elicit immediate and significant increases in the number of daily steps reported by participants with T2D.

However, the efficacy of pedometers in maintaining increased activity over the long-term, without additional support, has yet to be demonstrated.

2.6.3. Summary

Behaviour change interventions should be based on theory. Goal setting and self-monitoring are essential for the adoption and maintenance of physical activity. Self-monitoring allows the assessment of progress towards achieving goals. Walking, which is the activity most frequently performed by people with T2D, could be challenging to monitor as it is often less structured and salient than planned physical activities. However, pedometers offer timely and accurate self-monitoring of walking behaviour and have been shown to be useful at facilitating the adoption of physical activity. Moreover, their use appears to be feasible and acceptable to people with T2D.

2.7. Study rationale

Recent large cohort studies and intervention trials provide strong evidence for the value of physical activity and CRF in protecting against the development of T2D, particularly in individuals who are at high risk due to impaired glucose tolerance, obesity and family history of the disorder. Prospective observational evidence also shows that both physical activity and CRF are inversely associated with cardiovascular and all-cause mortality among people with T2D. Furthermore, evidence from intervention studies demonstrates that increased physical activity and improved CRF may be associated with improvements in glycaemic control and other metabolic and physiological outcomes in people with T2D.

Reported associations with health outcomes tend to be stronger for CRF than physical activity. This may be attributable to the differences in measurement error between the two exposures, as self-reported methods are typically used for the assessment of physical activity, while fitness will almost certainly be measured directly, either by submaximal or maximal testing procedures. Measuring physical activity is challenging because of its complex nature. Self-reported measures tend to be crude and imprecise, and they are likely to weaken the strength of observed associations with health-related outcomes. Consequently, the deficiencies in the measurement of physical activity complicate the interpretation of the results of epidemiological studies, and thus make it difficult to design appropriate interventions and to estimate the resultant benefit that could be expected.

Objective measures of physical activity using sensitive instruments, such as accelerometers, provide more accurate data that can enhance our understanding of the association between different dimensions of physical activity and health. Unfortunately, very few data have been published that describe objectively-determined habitual physical activity levels in adults with T2D. Moreover, the discrepancy in measurement precision between physical activity and CRF means the true independent cross-sectional associations of these with glycaemic control and other physiological outcomes in T2D remain unclear. It is therefore currently unknown which of physical activity and CRF is most important in managing the condition.

Accurate quantification of habitual activity in this population is required to inform activity promotion and intervention strategies. Furthermore, determining the relative importance of physical activity and CRF in relation to important health outcomes in people with T2D is necessary for the translation of research findings into clinical management, policy and practice recommendations.

The purpose of this study was to 1) develop intervention materials for the purpose of facilitating the initiation and maintenance of physical activity, 2) describe objectively measured habitual physical activity, 3) examine change in physical activity over six months, 4) explore the use of pedometers and diaries to monitor daily physical activity over a six-month period, 5) describe CRF levels, and 6) explore the independent and interactive cross-sectional associations of physical activity and CRF with HbA_{1c} and the clustering of cardiovascular risk factors among people with recently diagnosed T2D recruited to the Early ACTID Study.

Chapter 3. Methods

Whilst it is beyond the scope of this thesis to provide a detailed description of the Early ACTID methodology, the first section will offer an overview of the trial's methods, in order to put into context this PhD project. Subsequent sections will focus on the methods employed to conduct this PhD study and to meet the objectives outlined at the end of Chapter 1.

3.1. The Early ACTID Study

3.1.1. Background

The Early ACTID Study is an ongoing randomised controlled trial, designed to comply with the CONSORT guidelines. The aim of the study is to compare a 1-year programme of *diet plus home-based exercise* with *diet only* and *usual care* on glycaemic control, blood pressure, lipids and weight status in 550 adults with newly-diagnosed T2D. The study protocol was approved by Bath NHS Research Ethics Committee in September 2005.

3.1.2. Methods

Participants

The participant inclusion and exclusion criteria for the Early ACTID Study are summarised in Table 3.1.

Table 3.1. Inclusion and exclusion criteria for the recruitment of participants to the Early ACTID Study

Inclusion criteria	Exclusion criteria
• T2D • Between 5 and 8 months from clinical diagnosis • BMI >25 kg/m^2 • Aged between 30 and 80 years at diagnosis	• HbA_{1c} >10% • Ketosis • Resting blood pressure >180/100mmHg • LDL cholesterol >4mmol/l • Already receiving a maximum dose of a sulphonylurea • Current diagnosis of unstable angina • Myocardial infarction within the previous three months • Pregnant or planning to conceive within 18 months • Unable to increase physical activity

Sample size

Sample size was calculated by Dr. A Montgomery and Prof. T Peters at The Department of Primary Care, University of Bristol. Sample size was based upon the primary outcomes, HbA_{1c} and blood pressure. The standard deviation of HbA_{1c} among patients with diabetes has been reported as 1.87%, and a change of 0.5% in HbA_{1c} is regarded as the smallest worthwhile clinical difference (UKPDS Group, 1998). This equates to a standardized difference of 0.267. For systolic and diastolic blood pressure, with an observed standard deviation of 17 mmHg and 10 mmHg respectively, a standardised difference of 0.267 relates to a target difference of 4-5 mmHg for systolic blood pressure and 2-3 mmHg for diastolic blood pressure, both of which would be considered clinically important. With 80% power and 5% two-sided alpha, 217 participants were required in each group in order to detect these differences in the primary outcomes for the primary comparison of *diet plus exercise* versus *diet alone*. For the secondary comparisons of each of these versus standard care, an additional 62 participants randomised to standard care provides 45% power to detect a difference of about 0.4 standard deviations, allowing for multiple comparisons. Allowing for an attrition rate of approximately 10%, the target recruitment sample size was calculated to be 550.

Recruitment

Participants were recruited to the Early ACTID Study from the following South West NHS regions between November 2005 and June 2008:

- Taunton and Somerset NHS trust, covering Somerset;
- United Bristol Healthcare NHS trust, covering North Somerset;
- North Bristol NHS trust, covering the North Bristol; and
- Gloucestershire Hospitals NHS trust, covering Gloucestershire.

Each of the four regions had a dedicated consultant endocrinologist, a specialist diabetes dietitian, and a research nurse employed by the study who were based at the hospital site. The study's nurses were responsible for recruiting participants through regular T2D education courses run at local General Practitioner (GP) practices. Regular searches were also performed on GP database records. Treatment and follow-up of participants are planned to continue until July 2009.

Screening and informed consent

Individuals who expressed an interest in participating in the trial underwent telephone screening administered by a study nurse. Participants fulfilling the inclusion criteria were sent relevant information about the study. After having 14 days to read through the information, individuals had the opportunity to discuss the study with the research nurse during a follow-up telephone call. Participants who wished to enrol in the study were invited to attend a screening visit (Visit 1) that formally assessed their eligibility for the trial.

Once written consent was obtained by the research nurse at the start of the screening visit, participants had their height, weight and blood pressure measured. A non-fasting blood sample was then taken to assess participants' HbA_{1c}, lipid profile, liver function, thyroid function and full blood counts. Finally, questionnaires obtaining demographic and general health information were administered. At the end of the visit, the nurse arranged the baseline measurements and randomisation appointments.

Randomisation and allocation

Randomisation was stratified by centre and minimised on gender, age, fitness category, blood pressure and HbA_{1c}. Minimisation was used to limit differences between groups and reduce the risk of type 1 error (Kernan, Viscoli, Makuch et al., 1999). An automated system randomly allocated participants to one of the following groups during Visit 4 with the study dietitian:

I. Usual care

II. Dietary intervention

III. Dietary intervention plus exercise

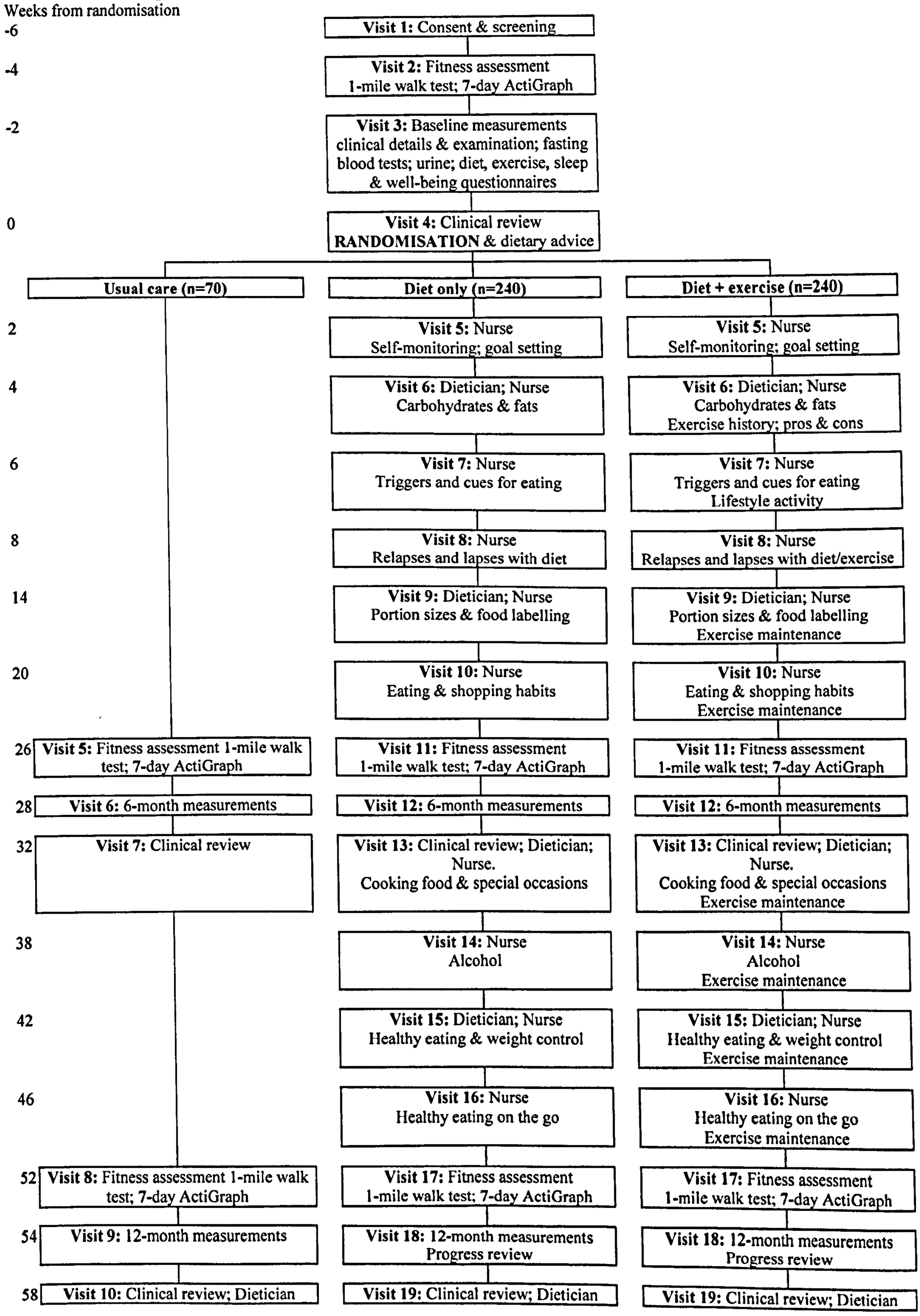
Protocol

Usual care group

Individuals randomly allocated the *usual care* group had ten scheduled visits throughout the study, which are outlined in Figure 3.1. Participants were given the opportunity to arrange an appointment with their study nurse between visits in the event of any problems.

Participants in this study arm received a Participant Record File (PRF) containing contact details for the Early ACTID staff taking over their care; information about the study, their study group and appointments; information on healthy eating principles for diabetes; and space for recording their medications,

Figure 3.1. Flow diagram of participant progress through the Early ACTID Study



measurement results, and personal notes. This version of the PRF was based on recommendations in the National Service Framework for Diabetes Delivery Strategy (Department of Health, 2003b) and by Diabetes UK (Diabetes UK, 2003), which relate to patient-held records. During the baseline dietitian appointment (Visit 4), participants were given standard advice about healthy eating, which, at the time, was provided by South West NHS trusts. This advice included eating regular meals, cutting down on fat, eating more fruit and vegetables, limiting sugar, using less salt, drinking alcohol in moderation, losing weight, and not buying special diabetic food. At their last trial visit (Visit 10), participants in the *usual care* group received a full set of PRF inserts (see Appendix 5 for a listing), which were developed for the intervention arms. These included comprehensive information on healthy eating, physical activity, self-monitoring, changing behaviours, and overcoming barriers (see Appendix 6).

Intervention groups

After randomisation, participants assigned to either the *diet only* or *diet plus exercise* group received five individually tailored sessions with their study dietitian at weeks 4, 14, 32, 42 and 58, and ten sessions with their study nurse at weeks 2, 4, 6, 8, 14, 20, 32, 38, 42, and 46. Each session lasted approximately 30 minutes and had a pre-planned topic to focus discussion, as outlined in figure 3.1. During nurse visits in the *diet plus exercise* group, time was equally divided between healthy eating and physical activity. In the *diet only* group, the nurse spent half of the visit discussing topics unrelated to the trial, in order to ensure that contact time between the intervention groups was equal. In total, participants in the intervention arms had 19 visits during the study.

Diet only group

The primary study goals for participants randomly assigned to the *diet only* group included 1) achieving a weight reduction of 5-10% of initial body weight within the first six months through healthy eating, and 2) maintaining the weight reduction of 5-10% of initial body weight in the second six months through healthy eating.

Previous studies have shown that a weight loss of 5-10% lowers plasma glucose and improves cardiovascular risk factors, with an apparent dose-response relationship between the magnitude of weight reduction and the improvement in these parameters (Colditz, Willett, Stampfer et al., 1990; Poirier, Giles, Bray et al., 2006; Selwyn, 2007). The recommended pace of weight loss was 0.5 to 1kg per week, which is considered to be safe, effective and feasible. Participants were encouraged to achieve the weight loss goals

by establishing a hypo-energetic diet, based on an energy deficit of approximately 500 kcal·day^{-1}. Although participants were weighed on a digital scale at the start of each nurse visit, they were also encouraged to weigh themselves at home once a week and to record their weight using the appropriate materials.

Diet plus exercise group

In addition to the dietary programme detailed above, participants randomly assigned to the *diet plus exercise* group received an exercise intervention, with the primary goal of engaging in an extra 30 minutes of brisk walking on five or more days of the week, performed in bouts of at least ten minutes.

Walking is the most frequently reported form of physical activity (Institute of European Food Studies, 1999) and has been found to promote better adherence than more intensive exercise (Dishman, 1994). Its widespread application lies in the fact that it requires no special skills or facilities and is achievable by virtually all age groups with little risk of injury. Walking has been described as 'the most convenient, low impact mode of physical activity for people with T2D' (American College of Sports Medicine, 2000) and 'the best medicine for diabetes' (Hu and Manson, 2003).

To enable the self-monitoring of physical activity, which has been shown to be positively associated with initiation and maintenance of physical activity (Bravata et al., 2007), *diet plus exercise* participants received a Yamax Digi-Walker (SW-200) pedometer, instruction materials for wearing and using the pedometer, and activity diaries (see Appendix 6, PA9 and 10) for use throughout the intervention. The Digi-Walker pedometer is a small device worn on a belt or waistband that measures vertical acceleration during bodily movements, and it is one of the most accurate pedometers available (Bassett, Ainsworth, Leggett et al., 1996). Due to their motivational nature, the pedometers were used primarily as an intervention tool, rather than an outcome measure.

Participants were instructed to wear the pedometer during all waking hours, except when showering, bathing or swimming, for the duration of the intervention. Participants were also asked to use the physical activity diaries, provided by the study, ensuring that each day they recorded: 1) the times that the pedometer was worn, 2) the duration of any bouts of activity lasting at least ten minutes, 3) the number of steps accumulated during activity bouts, 4) the final pedometer reading at the end of the day, and 5) any moderate-intensity activities that were performed in addition to walking, e.g. swimming.

During Visit 5, participants were shown how to locate the most accurate position for their pedometer. The long-term study goal of brisk walking for 30 minutes, accumulated in bouts of at least ten minutes, was

discussed with each participant. This volume and intensity of the exercise goal is in line with national guidelines (Department of Health, 2004) and has been shown to produce improvements in CRF, weight, percentage body fat, and overall health in non-clinical populations (Hardman, 2001). Participants were advised to achieve the goal gradually over five weeks in a step-wise fashion and then maintain the activity level for the remainder of the study. Long-term step goals were calculated on the basis that ten minutes of brisk walking (3-4 miles per hour) (Ainsworth et al., 2000) equates to approximately 1000 steps (Welk, Differding, Thompson et al., 2000). Since the aim of the activity intervention was to perform an additional 30 minutes of brisk walking on at least five days per week, participants were asked to accumulate an extra 3000 steps of brisk walking on most days.

Clinical measurements and questionnaires

Table 3.2 shows the clinical measurements, conducted by the research nurse, and the questionnaires completed by participants at baseline, six and 12 months. Protocols were developed for each measurement to ensure standardisation across sites and between visits. These protocols were developed by the principal investigator and research nurses.

Table 3.2. Clinical measurements and questionnaires completed at baseline, six and 12 months

Clinical details
- Diabetes history
- Past medical history
- Drug history
- Family history
- Social history

Clinical examination
- Cardiovascular, respiratory, gastrointestinal and central nervous system examinations
- Height
- Weight
- Waist circumference
- Body fat content (Bio-impedance)
- Blood pressure

Other investigations
- Early morning urine sample (Albumin/Creatinine ration and Dipstick)

Questionnaires
- Stage of change towards diet
- Self efficacy towards diet
- Physical activity readiness questionnaire (PARQ)
- Stage of change towards exercise
- Self-efficacy towards exercise
- Process of change for exercise
- Social support for physical activity scale
- Decisional balance for exercise
- Outcome expectations for exercise

Fasting blood tests
- Blood lipids, including cholesterol, HDL cholesterol, LDL cholesterol and triglycerides
- Insulin resistance and insulin secretion (2 fasting glucose and insulin tests, 5 minutes apart)
- Inflammatory markers (e.g. Adiponectin, high sensitivity CRP, IL6 and IL10)
- EDTA blood for DNA extraction
- EDTA blood for HbA_{1c}

3.2. PhD aims and hypotheses

The measurement of cardiorespiratory fitness was not part of the original study proposal and the addition of this measure by the researcher thus added a unique aspect to the study. In addition, the researcher was responsible for developing a physical activity intervention programme suitable for individuals with T2D based around the use of a participant-held record file (PRF).

As highlighted at the end of the Introduction chapter, the aims of the PhD were to:

- develop intervention materials for the purpose of facilitating the initiation and maintenance of physical activity in *diet plus exercise* participants of the Early ACTID Study,
- describe objectively measured physical activity levels in people with newly diagnosed T2D,
- examine the six-month change in physical activity among participants in the Early ACTID Study.
- explore the use of pedometers and diaries to monitor daily physical activity over a six-month period in participants randomised to the *diet plus exercise* intervention of the Early ACTID Study,
- describe CRF levels in people with newly diagnosed T2D,
- explore the independent associations of objectively measured physical activity and CRF with HbA_{1c} and the clustering of cardiovascular risk factors in people with newly diagnosed T2D, and
- investigate whether there is an interaction effect between physical activity and CRF on HbA_{1c} and the clustering of cardiovascular risk factors in people with newly diagnosed T2D.

The hypotheses for this study are shown below. Exposure and outcome variables for each hypothesis are detailed in the 'Data and analyses' section of this chapter.

H1. Physical activity is associated with HbA_{1c} in people with T2D

H2. $VO_{2max.pred}$ is associated with HbA_{1c} in people with T2D

H3. $VO_{2max\ pred}$ modifies the association between physical activity and HbA_{1c}

H4. Physical activity is associated with the metabolic syndrome in people with T2D

H5. $VO_{2max.pred}$ is associated with the metabolic syndrome in people with T2D

H6. $VO_{2max.pred}$ modifies the association between physical activity and the metabolic syndrome in people with T2D

3.3. Study design

This thesis will present cross-sectional data from the Early ACTID Study cohort. Cross-sectional data obtained at both baseline and six months will be presented in order to illustrate the consistency of relationships. Although change in physical activity over a six-month period has been examined in order to assess compliance with the physical activity study goals, at the time of writing the Early ACTID RCT was ongoing and it was therefore not considered appropriate to analyse data to determine differences in key clinical outcomes between study groups. Data have therefore been analysed to examine differences between cohort subgroups and these will be presented in the following chapter of this thesis.

3.4. Participants

Baseline analyses included participants who had undergone baseline measurements by June 2007. Follow-up analyses included participants who remained in the study at six months. Physical activity diary data from participants in the *diet plus exercise* group are reported for the first six months of the intervention.

3.5. Intervention materials

3.5.1. Features of the intervention groups

Key features of the interventions are outlined in Table 3.3. These features were based on previous studies that have been successful in facilitating long-term lifestyle change among participants with impaired glucose tolerance (Diabetes Prevention Program Research Group, 2002) and T2D (Di Loreto et al., 2003; Kirk et al., 2004b).

The goal of both interventions was to provide participants with the necessary knowledge and skills to achieve gradual behavioural changes that could be sustained permanently. Specifically, the interventions had been designed to incorporate strategies and techniques that are known to influence the mediators of change, including self-efficacy, decisional balance, and processes of change (Marcus and Simkin, 1994), as described in the previous chapter.

Table 3.3. Key features of the Early ACTID Study's interventions

- Frequent contact
- Structured protocol, with the flexibility to tailor strategies individually
- Clearly defined long- and short-term goals
- Interactive participant-held record files (PRF)
- Education
- Self-monitoring tools
- Problem solving
- Relapse prevention
- Ongoing, individually-tailored intervention

Frequent contact and ongoing support were considered essential components of the *diet only* and *diet plus exercise* interventions, particularly in the initial few months while participants made significant changes to their lifestyles. To ensure standardisation across sites and between appointments, the researcher developed a standard operating procedure (SOP) for each visit (see Appendix 7) and a pre-planned curriculum of topics was agreed (see figure 3.1). Although a structured protocol and curriculum was required to ensure that all participants were provided with the same information, the SOP also allowed the nurses and dietitians to tailor sessions according to each participant's individual needs, thus maintaining a patient-centred approach.

3.5.2. Development and use of the participant record file

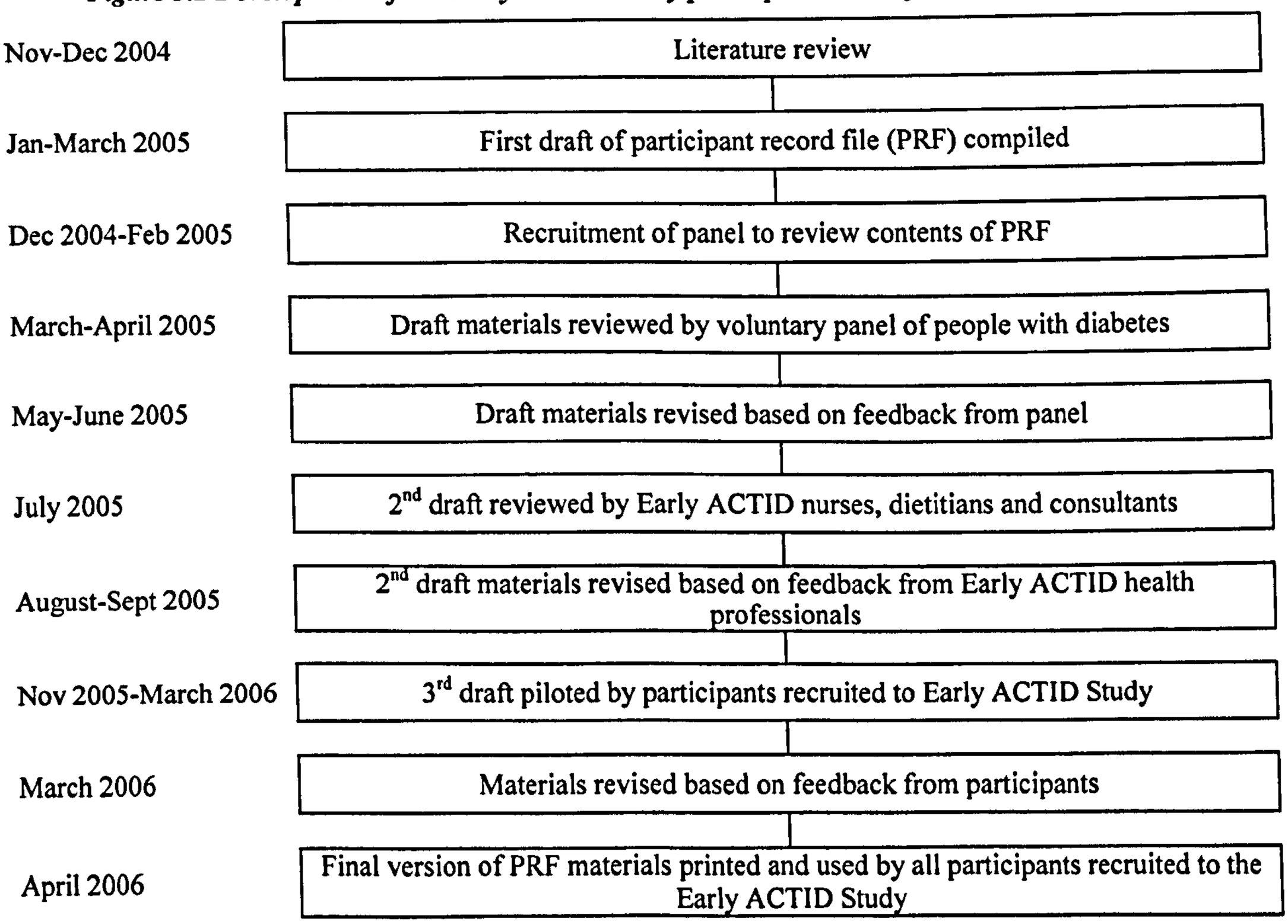
Rationale and purpose of the PRF

Patient-held records are increasingly being used in healthcare settings as they are thought to encourage partnership between healthcare professionals and patients. Interventions that involve patient collaboration are considered to be more effective than didactic interventions in improving glycaemic control, weight and lipid profiles (Norris, Engelgau and Venkat Narayan, 2001). In diabetes care, the empowerment and engagement of the individual with the condition is one of the 12 standards in the National Service Framework (NSF) for Diabetes (Department of Health, 2001). Self-management is often described as the cornerstone of good diabetes control and, hence, the patient's involvement in decision-making is clearly an important part of diabetes care. The NSF's vision is to 'offer care that is structured and pro-active, providing people with the support they need to manage their own condition' (Department of Health, 2003b). To assist with this, the NSF's delivery strategy recommends 'a personal diabetes record containing a clinical record of care, treatment and management that is held by the person with diabetes and used by

Counterweight Project Team, 2004a; The Counterweight Project Team, 2004b) and *Steps to better health* (The Cooper Institute, 2003).

The tools and materials forming the basis for the development of the Early ACTID PRF were primarily grounded in theories and principles of behaviour change and physical activity counselling and consultations (Kerr, Weitkunat and Moretti, 2005; Kirk and De Feo, 2007; Kirk et al., 2007; Kirk et al., 2004b; Marcus and Forsyth, 2003; Rollnick, Butler, McCambridge et al., 2005; Rollnick, Mason and Butler, 2002).

Figure 3.2 Development of the Early ACTID Study participant record file (PRF) materials



Theoretical framework

The reviewed materials from interventions that have reported significant increases in physical activity are primarily based on the transtheoretical model, which emphasises the importance of three mediators of change, including self-efficacy, decisional balance and processes of change, as described in the previous chapter. This model proposes that interventions designed to facilitate adoption and maintenance of a particular behaviour should be tailored to the stage of readiness of the individual concerned. Since all Early

them and the diabetes team' (p14-15) (Department of Health, 2003b). The strategy suggests the record should include:

- an agreed care plan, including education and the personal goals of the person with diabetes;
- how their diabetes is to be managed until their next review to foster greater understanding and ownership of the goals of diabetes care;
- the identification of health, social care and educational needs, how they will be met and who will be responsible;
- a named contact.

The use of patient-held records as part of diabetes care is also advocated by Diabetes UK, and their potential role in encouraging patient involvement and engagement has been acknowledged (Diabetes UK, 2002). Consequently, a patient-held record could be viewed as a useful diabetes management and communication tool that benefits both healthcare professionals and the patient. A pateint-held record file (PRF) thus represented a relatively inexpensive, practical intervention tool that could be used to faciltate behavioural change in participants recruited to the Early ACTID Study.

In the present study, the main purpose of the PRF was two-fold: 1) to facilitate participant involvement and behavioural change, and 2) to assist the nurses in delivering the intervention by providing structure for participant visits and interactive materials that enabled the nurses to support participants in adopting and maintaining new health behaviours. The materials themselves were developed to encourage self-monitoring and to increase motivation to change and self-efficacy to make and maintain changes (see Appendix 6).

Development process

Figure 3.2 outlines the different stages of the PRF development process. With the exception of the dietary information materials, which were developed by a team from the Nutrition and Health Research Group at the MRC, the PRF contents were designed and developed by the researcher. In addition to reviewing recommendations and suggestions relating to the clinical contents of a patient-held record, materials from interventions and programmes that have been successful at facilitating the adoption and maintenance of physical activity were reviewed. Resources from interventions involving adults with T2D or impaired glucose tolerance were prioritised. The reviewed materials included the *Diabetes Prevention Program* study (Wing and Gillis, 1996), *The Counter Weight Programme* (The Counterweight Project Team; The

Counterweight Project Team, 2004a; The Counterweight Project Team, 2004b) and *Steps to better health* (The Cooper Institute, 2003).

The tools and materials forming the basis for the development of the Early ACTID PRF were primarily grounded in theories and principles of behaviour change and physical activity counselling and consultations (Kerr, Weitkunat and Moretti, 2005; Kirk and De Feo, 2007; Kirk et al., 2007; Kirk et al., 2004b; Marcus and Forsyth, 2003; Rollnick, Butler, McCambridge et al., 2005; Rollnick, Mason and Butler, 2002).

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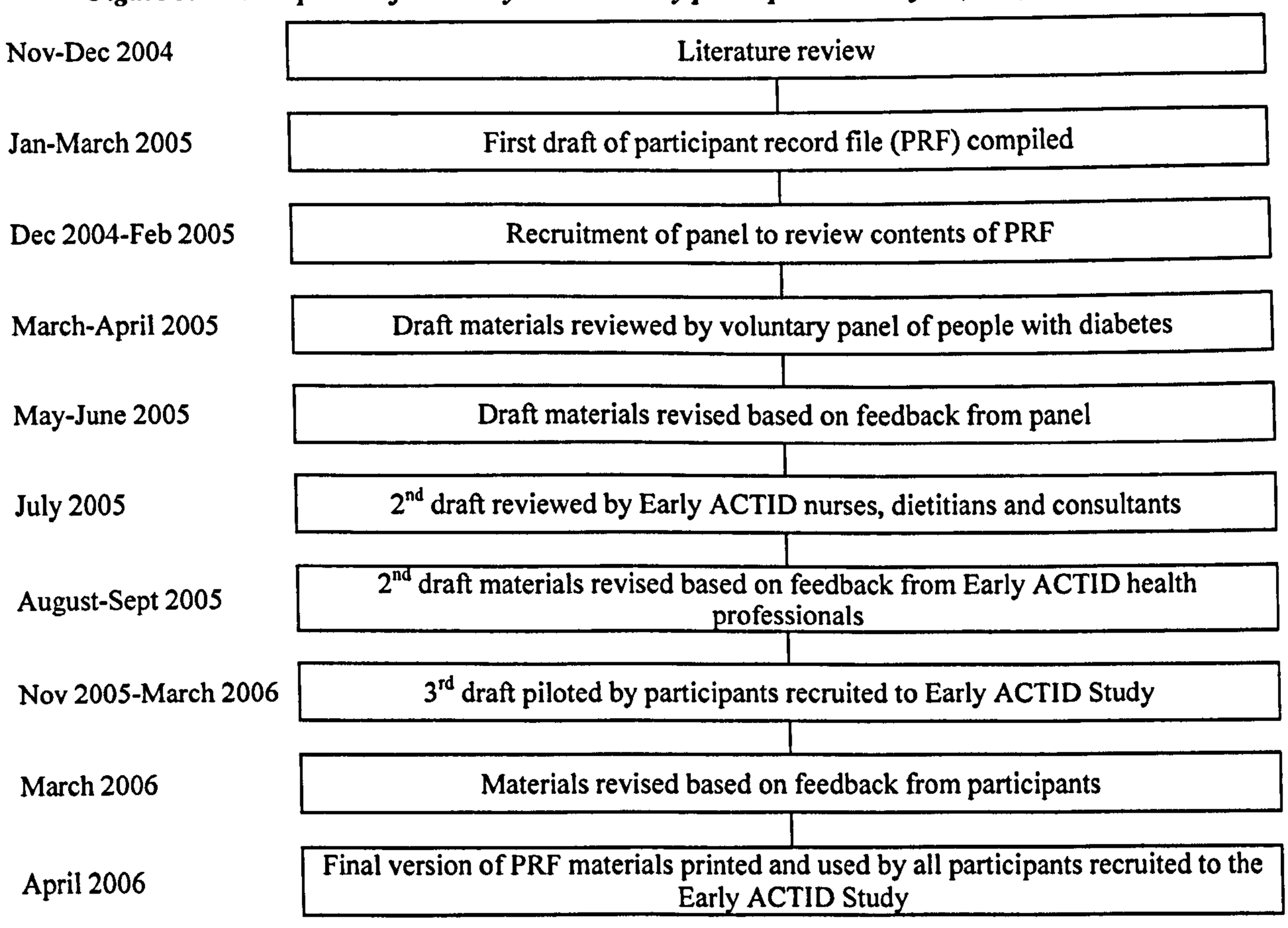


Theoretical framework

The reviewed materials from interventions that have reported significant increases in physical activity are primarily based on the transtheoretical model, which emphasises the importance of three mediators of change, including self-efficacy, decisional balance and processes of change, as described in the previous chapter. This model proposes that interventions designed to facilitate adoption and maintenance of a particular behaviour should be tailored to the stage of readiness of the individual concerned. Since all Early

ACTID participants had volunteered to enter a study in which a willingness to increase physical activity was an inclusion criterion, the materials were predominantly tailored towards the contemplation, preparation and action stages, since one of their main aims was to facilitate behavioural change.

Studies have shown that the cognitive and behavioural strategies which are most strongly associated with physical activity include self-monitoring, goal setting, feedback, support, evaluation of progress and identification of barriers for relapse prevention (Calfas et al., 1997; Writing Group for the Activity Counseling Trial Research Group, 2001). These strategies formed the basis of the PRF physical activity materials, which are described below.

Format and contents of the PRF

The PRF consisted of 106 double-sided pages containing information, worksheets, charts and records. The file comprised of five colour-coded sections: 1) Information, 2) Healthy eating, 3) Physical activity, 4) Progress reports, and 5) Personal notes. In line with Diabetes UK care recommendations on patient-held records (Department of Health, 2003b), the ring binder file was A5 size, so that it could be easily transported to and from appointments, and the binder itself was made of clear frosted polypropylene, in order to protect it from general wear and tear over the course of the programme. The contents of the file were produced as individual loose leaves so that pages could be added or removed at different times throughout the study.

During the year-long Early ACTID programme, the physical activity inserts were given only to those participants randomised to the *diet plus exercise* group. At the end of the programme, participants randomised to the other two groups were offered all materials developed for the interventions.

The physical activity section of the PRF was primarily based on principles of behaviour change and key components of interventions that have been successful at increasing physical activity levels among participants and maintaining increased levels over time. The main aim of the PRF materials was to facilitate participant involvement and behavioural change. Interactive materials were developed for the participant record file (PRF) to encourage self-monitoring and to increase motivation to change and self-efficacy to make and maintain changes (see Appendix 6). The physical activity section of the PRF consisted of the following four subsections:

1) Keeping track

Previous studies have demonstrated the effectiveness of pedometers and activity diaries in terms of eliciting immediate and significant increases in physical activity (Bravata et al. 2007). Furthermore, they have been found to enhance self-efficacy (Gleeson-Kreig, 2006) and appear to be acceptable to adults with diabetes (Tudor-Locke, Myers, Bell et al., 2002b). Self-monitoring using these tools was a key feature of the intervention programme and was one of the first topics addressed with *diet plus exercise* participants after randomisation. The 'Keeping track' subsection of the PRF aimed to highlight the importance of monitoring physical activity levels. All inserts within this section were provided in Visit 5. A pedometer was also provided at this visit and participants were asked to wear it daily and to record their total daily steps and bouts of physical activity using the diaries provided in the 'Physical activity diary' subsection. A physical activity graph was available for recording the total number of steps walked day-by-day. The purpose of this graph, found in the 'Progress reports' section, was to enable participants to easily see their progress over time. During each visit, the nurse briefly reviewed the self-monitoring sheets with the participants and reinforced any positive changes. All physical activity diary data was entered into a database by the nurse at each visit so that adherence to the intervention could be monitored over the course of the programme. Once the data had been entered, the diaries were returned to the participants.

2) Goals and plans

Bravata and colleagues (2007) found that step goals and diaries were key intervention characteristics associated with increased physical activity. As such, personalised goal setting was a key aspect of the intervention and was a key feature of each visit. Participants were encouraged to set specific and measurable goals that were acceptable and realistic within the context of their life.

Choosing achievable and realistic goals is important for enhancing self-efficacy, since positive mastery experiences are associated with increased confidence, which, in turn, is fundamental to successful behavioural change (Marcus and Forsyth, 2003; Rollnick et al., 2002). Equally, the failure to achieve goals will adversely affect an individual's confidence in their ability to reach a particular goal, and thus gradually increasing physical activity levels over a number of weeks was an important phase of the intervention.

The long-term intervention goal for participants in the *diet plus exercise* group was to engage in an additional 30 minutes of moderate intensity activity on five or more days each week. In order to prevent compensatory behaviour, where individuals may increase the time spent in discrete bouts of activity but not

increase the overall volume of daily activity, participants were advised to build up to accumulating at least an additional 3000 steps, on top of what they were accumulating at baseline.

Physical activity counselling principles recognise that an individual's motivation and confidence in relation to a goal must be reasonably high if the goal is to be achieved. A useful strategy for assessing these involves the scoring of each on a 0-10 scale, where 0 is not at all motivated or confident and 10 is extremely motivated or confident. This strategy was incorporated into the 'physical activity goals' worksheet in an attempt to encourage participants to select achievable and realistic goals. To further enhance self-efficacy, participants were supported in planning when, where and how they were going to achieve their goals.

At each visit, the nurse and participant reviewed the goals set at the previous visit. Successes and difficulties in relation to achieving their goals were discussed and recorded in their file (PA.16). Successes were addressed because performance accomplishment or mastery is known to be strongly influence self-efficacy, which in turn predicts physical activity behaviour. Addressing difficulties allowed the participant and nurse to discuss how these could be minimised or avoided in the future.

3) Information sheets

The 'Information sheets' subsection contained general information that was related to participating in the *diet plus exercise* intervention. Materials covered troubleshooting the pedometer, facts about walking, foot care, illness, hypoglycaemic episodes and stretching. There were no interactive materials in this subsection.

4) Gaining confidence

The aim of this subsection was to reinforce motivation to increase physical activity and to enhance self-efficacy to make and maintain changes. Materials were based on cognitive-behavioural strategies that have been shown to influence physical activity behaviour. The majority of inserts were interactive so that they could be tailored to the participant's own situation. The first five inserts were provided over the course of three visits. These related to the following topics:

- Physical activity history
- Benefits and perceived pros and cons of physical activity
- Lifestyle activity
- Opportunities to be active
- Preventing relapses

The final four inserts were optional materials that could used to help participants overcome their perceived barriers to physical activity. These inserts were used from visit 7 onwards and included:

- Barriers to physical activity
- Personal time diary
- People to help you achieve your goals
- Local exercise opportunities

Piloting

To ensure that the record file materials were appropriate for people with newly diagnosed T2D volunteers from a local Diabetes UK support group were asked to read the draft PRF materials and to comment on their readability and content. A brief description of what would be involved was provided to all members of the group (see Appendix 7) and those who indicated an interest were sent an email or letter inviting them to attend a short presentation, which provided an overview of the research project and explained the purpose of reviewing the draft materials. Potential volunteers were advised that they would not be required to use or complete the materials. In order to minimise inconvenience, the presentation took place before the start of their usual support group meeting. After the presentation, seven adults with T2D volunteered to review the draft PRF contents. Volunteers included both individuals with a recent diagnosis and individuals with established T2D. Each volunteer was given at least two weeks to read through the materials and consider 1) readability, 2) content, and 3) additional items that would be useful for people recently diagnosed with T2D. Volunteers were asked also to review five sample pages at the end of the document. Each page was typed using a different font and volunteers commented on the font's readability and indicated their preferred options. One-to-one meetings were held with the volunteers in order to discuss their comments in detail.

Where appropriate, the PRF materials were revised according to the feedback obtained from the volunteers. The second draft version was reviewed by a number of health professionals, including nurses, dietitians and consultants who provide diabetes care. After additional revisions, based on feedback provided by the health professionals, the PRF materials were piloted with the first 30 participants randomised to the trial. Between two and three months after randomisation, qualitative feedback about the materials was obtained from a sub-sample of ten participants who participated in a telephone interview. The final version of the

PRF contains five colour-coded sections and several subsections. A list of materials developed for the PRF is provided in Appendix 5.

Use of the participant record file

Sessions delivered by the nurse were structured according to the standard operating procedures developed by the researcher (see Appendix 8) and were based around inserts developed for the PRF (see Appendix 5 and 6). In general, each nurse session included the following:

- Bodyweight measurement
- Review of previous self-monitoring goals
- Discussion of successes and difficulties/barriers in relation to previously agreed goals
- Presentation of a new topic with corresponding PRF materials
- Agreement of new behavioural goals and action plans

3.5.3. Monitoring physical activity levels

After randomisation, participants in the *diet plus exercise* group were asked to maintain their usual activity levels during the first two weeks of using the pedometer and diaries in the PRF. Once the physical activity logs had been returned at the following visit, the nurse entered the recorded data into a Microsoft Excel workbook (see Appendix 9), developed by the researcher, specifically for the entry of physical activity diary data. Physical activity entered for the initial two weeks of recording was used as a baseline measure of steps.

For the purpose of monitoring compliance, all recently completed activity logs were reviewed and entered into the study's database after each visit. A summary page on the database showed the total and daily average steps, time spent brisk walking, and time spent in other moderate physical activities for each participant (see Appendix 9). The number of days per week that the step and time targets had been achieved were also calculated and shown on the summary page. Perceived barriers were explored with participants who were not achieving the physical activity goal, and appropriate materials from the PRF were used to help overcome barriers and facilitate physical activity adoption and maintenance.

3.6. Measurements

3.6.1. Physiological and metabolic outcomes

All outcome measures were performed at baseline and at six months post randomisation. Height and weight were assessed by the study nurses using standardised procedures. Participants were barefoot and wore only light indoor clothing for anthropometric measurements. Height was measured to the nearest 1cm using a stadiometer (SECA). Weight was recorded to the nearest 0.1kg using calibrated digital scales. BMI was calculated as weight in kilograms divided by the square of height in metres (kg/m^2) and classified according to the following NICE criteria (National Institute for Health and Clinical Excellence, 2006), as shown in Table 3.4.

Table 3.4. Classification of weight status according to BMI

BMI (kg/m^2)	Classification
<18.5	Underweight
18.5-24.8	Healthy weight
25.0-29.9	Overweight
30.0-34.9	Obese I
35.0-39.9	Obese II
≥40	Obese III (morbidly obese)

Prior to the physiological and metabolic measurements, participants were required to: 1) fast, with the exception of water, for at least ten hours, 2) not take any morning medication, and 3) abstain from smoking for at least 30 minutes. The research nurse performed these measurements using standardised measurement protocols developed by the trial's nurses and doctors. Blood pressure was assessed according to measurement protocols adapted from the British Hypertension Society (BHS) Guidelines (Williams, Poulter, Brown et al., 2004). Briefly, once the participant had been supine for five minutes, three measures were taken at five-minute intervals using an automated blood pressure monitor (Omron 711) and appropriately-sized cuff, which was placed on the non-dominant arm. A mean of the three measurements was calculated.

Blood specimens were taken using appropriate vacutainer bottles to assess the parameters in Table 3.2. Once samples had been collected and handled appropriately (centrifuge where necessary) they were stored locally in hospital freezers at minus 80 degrees. Dry-ice was used for the transfer of samples from the local

centres to the co-ordinating centre to ensure samples were not affected by thawing. At the co-ordinating centre, samples were placed in designated freezers. Aliquots of the samples were sent in batches from the co-ordinating centre to the analytical and collaborating laboratories. Once the samples had been tested, the remainder of the aliquot was destroyed by the commercial testing laboratory. The remaining samples were retained at the co-ordinating centre.

Data Reduction

For the purpose of describing the study population, and also for performing exploratory analyses, glycaemic control was assessed by categorising the continuous variable HbA_{1c} according to guidelines published by NICE (National Institute of Clinical Excellence (NICE), 2002), as shown in Chapter 2.

A dichotomous metabolic syndrome variable was created according to the International Diabetes Federation (IDF) consensus definition of the metabolic syndrome (International Diabetes Federation, 2006). Participants with a BMI ≥30 and at least one of the factors listed below were categorised as having the metabolic syndrome:

- Triglycerides ≥1.7mmol/L
- HDL-cholesterol ≤1.03mmol./L in men and ≤1.29mmol/L in women
- Systolic blood pressure ≥130mmHg or diastolic blood pressure ≥85mmHg, or treatment of previously diagnosed hypertension

The diagnosis of diabetes in all participants excluded the use of the NCEP ATP III criteria for classifying participants in this study population with or without the metabolic syndrome. Of those definitions that are appropriate for people with diabetes (IDF, NCEP ATP III, and WHO), only the IDF criteria account for anti-hypertensive and anti-hyperlipidaemic medication use, which was highly prevalent among participants in the Early ACTID Study. Furthermore, the incomplete ascertainment of waist circumference provided an additional reason for the preclusion of the NCEP ATP III definition. Consequently, the IDF criteria were considered to be the only suitable criteria for assessing metabolic syndrome status within this study cohort.

3.6.2. Physical activity (ActiGraphs)

ActiGraph accelerometer

Habitual physical activity was assessed objectively with the ActiGraph GT1M activity monitor over a seven-day period. The ActiGraph monitor is a uniaxial accelerometer, which has a real-time internal clock that enables the monitor to start recording data at a desired time and to sum data over a user-defined interval (epoch). To begin collecting data, the monitor is initialised using ActiGraph software on a computer. Once the monitor has been downloaded on the computer, data collection automatically ends and the stored data can be viewed. The ActiGraph output is the summed amount and magnitude of accelerations for each epoch, displayed as counts, which can then be used to estimate the intensity of physical activity over time.

Procedure

Each ActiGraph was initialised, according to the manufacturer's instructions, to start summing physical activity counts at 60-second intervals from 5am the morning following the participant's fitness assessment. At the end of each fitness appointment, the ActiGraph was provided in a pouch on an elastic belt that could be adjusted according to the size of the participant's waist. An information sheet about the ActiGraph was also provided, together with an activity diary (Appendix 10) where each day participants were asked to record the day, date, time the monitor was put on and taken off, and whether the monitor was removed during waking hours. The diary also contained space for recording details of any physical activities performed that the ActiGraph was not able to record accurately, including seated and water-based exercise.

The ActiGraph was positioned over the right hip and worn during all waking hours for seven consecutive days, except during water activities, commencing the day following the fitness assessment. Participants were advised to maintain their usual lifestyle and level of physical activity during the measurement period.

The ActiGraph and physical activity diary were returned to the participant's Early ACTID nurse at the following appointment, which was scheduled between eight and 14 days after the fitness assessment. Once returned, these were passed to the researcher so that the monitors could be downloaded for subsequent analysis.

Data Reduction

The ActiGraph data were reduced with a custom macro, written in Microsoft Excel, that was developed for processing accelerometer data. The macro summed minute-by-minute activity counts for each hour of measurement. In addition, the macro was able to calculate the number of minutes of moderate to vigorous physical activity (MVPA) accumulated during each registered hour, using a cut point of ≥2100 ct·min^{-1}, which has been established in previous calibration studies of the ActiGraph monitor involving healthy participants (Brage et al., 2003; Freedson et al., 1998; Matthews, 2005; Yngve, Nilsson, Sjostrom et al., 2003).

For comparison of weekday and weekend activity, all files were aligned Monday through to Sunday, with 5am defining the start of each day. Periods of zero values for one hour or more were excluded from the analyses. To ensure the daily data were representative, only those days that contained at least ten registered hours (defined as >0 ct·h^{-1} recorded) were included. The criterion of ≥10 hours in order to constitute a valid measurement day was applied to maximise reliability and validity, as demonstrated by a number of studies (Corder, Brage and Ekelund, 2007; Esliger and Tremblay, 2006; Macfarlane, Lee, Ho et al., 2006). A measure of activity volume was calculated for each measurement period by dividing total activity counts by the number of registered hours to provide a mean value of counts per hour. This was then converted to mean counts per minute to allow comparisons with other studies. Once reduced (See Appendix 11 for the Actigraph reduction protocol), all summary data were entered into the Statistical Package for Social Science (SPSS) version 14.0, which was used to perform the analyses.

For the purpose of comparing outcomes between groups based on different activity levels, physical activity was categorised in three ways: 1) quartiles of activity volume, 2) quartiles of time spent in MVPA, and 3) achievement of physical activity recommendations, including i) accumulating 150 minutes of MVPA over seven days, or ii) accumulating ≥30 minutes of MVPA on at least five out of seven days. Sedentary levels of activity were defined as <30 minutes of MVPA over seven days (Department of Health, 2004).

Pedometers

Each participant in the *diet plus exercise* group received a Digi walker pedometer at the start of the intervention programme. Daily logs of physical activity were recorded by participants and handed in at each visit. Data recorded in the diaries were entered into a Microsoft Excel workbook, developed by the researcher, and analysed to assess compliance (see Appendix 9).

Data reduction

Total steps and the daily average steps per week were entered into SPSS for analysis. The number of days that each participant walked an extra 3000 steps above baseline values was also examined, since 3000 steps are thought to correspond with approximately 30 minutes of brisk walking (Welk et al., 2000)(reference needed here to support this statement). Thus, participants were asked to walk an additional 3000 steps on at least five out of seven days per week. Baseline values were calculated from the first two weeks of monitoring. Six-month values were calculated using means from data recorded during the preceding month (weeks 23 to 26).

3.6.3. Cardiorespiratory fitness (1-MTW)

The 1-Mile Track Walk test

The 1-Mile Track Walk (1-MTW) test, also referred to as the Rockport Fitness Test, is a widely used and validated submaximal field test that requires subjects to walk on a level track at a brisk and steady pace for one mile (Kline et al., 1987). Regression equations for the 1-MTW, which use body weight, age, gender, walk time, and post exercise heart rate, have been developed based on data collected from a sample of 390 healthy adults, aged 30 to 69 years, who performed a minimum of two 1-MTWs on separate days, and a maximal treadmill test (Kline et al., 1987). The reliability of the 1-MTW time and heart rates for the two track walks were .93 (SEE=0.26 minute) and .92 (SEE=7.6 bpm), respectively (Kline et al., 1987). The validity of the regression equation, established by correlating the predicted VO_{2max} ($VO_{2max.pred}$) and actual VO_{2max} was .93 (SEE=0.325 $L \cdot min^{-1}$) for the validation group (n=174) and .92 (SEE=0.355 $L \cdot min^{-1}$) for the cross-validation group (Kline et al., 1987).

The 1-MTW test eliminates the need for expensive equipment and maximal effort from the individual being tested, minimises associated risks, and offers the opportunity to identify potential participants who would be unable to increase their walking. Furthermore, it enables VO_{2max} to be estimated across a range of age groups and fitness levels. As such, the 1-MTW was deemed the most appropriate test for predicting cardiorespiratory fitness in participants recruited to the Early ACTID Study.

Procedure

Each participant attended their fitness assessment between seven and 14 days after their screening appointment (Visit 1). They were provided with information sheets detailing what the fitness test involves,

how they should prepare beforehand, a description of the 'Rating of Perceived Exertion' scale (Borg, 1973), and directions to the visit site (see Appendix 12). After Visit 1, the Early ACTID nurse completed a participant information form for the fitness test researcher, which detailed participant contact and appointment information, as well as gender, date of birth, height, weight and medication. Any other health conditions that were present were recorded also. Each assessment lasted approximately 30 minutes and was conducted on an indoor level track located at a sports centre within the region of the participant's hospital. Specific site and track details can be located in Appendix 13. Participants were asked to wear casual clothing and comfortable, supportive shoes appropriate for walking.

A measurement protocol for conducting the fitness appointment (Visit 2) was developed by the researcher to ensure standardisation (see Appendix 13). In order to assist the researcher administering the assessment, the data entry form completed during the visit was designed to also incorporate protocol prompts (See Appendix 14).

Once the participant arrived for their assessment, they were greeted and taken to the 1-MTW area. The area for testing was reserved for the fitness test appointments and closed to other individuals. The appointment started with a series of health and safety questions, detailed on the data entry form, to determine whether there were any reasons why the test should not be started. A heart rate monitor (Polar T61) was then fitted, comprising a transmitter strap worn around the chest and a receiver watch on the wrist, which was used to measure the participant's heart rate at rest and during the 1-MTW. A full briefing about what to expect and the opportunity to ask any questions was given prior to starting the warm-up.

The warm-up walk was performed by all participants and involved walking approximately 120 meters round the indoor track, starting slowly and gradually increasing the pace to a brisk walk. During the warm-up, the participant was asked how hard they felt they were exercising based on the 'Rating of Perceived Exertion' scale. The researcher used the participant's rating to indicate whether they should increase or reduce their walking speed for the actual 1-MTW, to ensure they were exercising between 13 ('Somewhat hard') and 15 ('Hard') on the Borg Scale (Borg, 1973), which is an intensity considered appropriate for predicting VO_{2max}. At the end of the warm-up, the participant was asked to march briskly on the spot, while the researcher recorded their post warm-up heart rate. The participant was then instructed to start the 1-MTW, and timing (using a stopwatch) began as soon as the participant's foot crossed the start line.

During the test, standardised encouragement was provided at the end of each lap, together with the number of laps completed and remaining, e.g. 'ten down and four to go; well done'. Every time another lap was walked, the elapsed time and participant's heart rate was recorded on the data entry form. At each quarter-mile point, the participant was asked to rate their perceived exertion. Participants who reported a rating below 13 or above 15 were advised to adjust their walking speed accordingly. As soon as the participant crossed the 1-mile marker, their heart rate and total time taken was recorded. For those individuals who were unable to complete the 1-mile distance, the time to complete the last full lap was recorded and used to predict 1-mile time (Donnelly, Jacobsen, Jakicic et al., 1992). A non-completion code was recorded on the data entry sheet, with a brief description of the reason(s). Indications for stopping the walk test included the onset of chest pain or angina-like symptoms, unusual or severe shortness of breath, unusual or severe musculoskeletal discomfort, symptoms of hypoglycaemia, physical or verbal manifestations of severe fatigue, participant's request, or failure of the testing equipment.

Upon completion of the test, the participant continued to walk at a slower pace for several minutes, until the heart rate had stabilised. Once stabilised, the participant was offered stretches and was then provided with an ActiGraph accelerometer. At the end of the appointment, the heart rate monitor was removed and the participant was free to rest. Changing room and shower facilities were available at all sites.

Data reduction

Data collected during the 1-MTW were entered into a Microsoft Excel worksheet designed to estimate VO_{2max} from the following regression equation.

132.853 - (0.0769 × Weight[lbs]) - (0.3877 × Age[yrs]) + (6.315 × Gender[female, 0; male, 1]) - (3.2649 × Time to complete 1 mile[mins]) - (0.1565 × Final heart rate[bpm])

Participants were categorised according to the six gender- and age-specific fitness groups, presented in Table 2.4 in chapter 2, which are based on cut off points derived from the Aerobics Center Longitudinal Study cohort. For the purpose of analysing the association between CRF and outcome variables, alternative fitness categories were created by dividing participants into gender-specific CRF quartile groups based on valid predicted VO_{2max} values. Values were considered to be valid if the participant: 1) completed the 1-mile distance within 20 minutes, 2) was not prescribed beta blockers, and 3) had a final heart rate that was not higher than 100% of their age-predicted maximum. For some analyses, the two lower and two higher fitness groups were also combined to represent individuals with low fitness and high fitness, respectively.

3.7. Data and analyses

3.7.1. Data checking

All analyses were performed using SPSS version 14.0. A missing value code was entered for variables with missing data. The distributions of the demographic variables and each exposure and outcome variables were examined for possible errors and outliers. This involved checking ranges and using appropriate graphical illustrations, such as histograms and scatter plots. Possible errors were checked against original records and corrected accordingly. Existing cases with values that were not viable were replaced with a missing value code. Borderline cases, where the value was an outlier but not considered impossible, remained unchanged. The distribution of each variable was re-examined to check that required corrections had been made.

Skewness and kurtosis were examined for each variable to assess departures from normality. Since the sample size in this study was considered to be large (>200), formal tests to assess the distribution of variables were not considered appropriate because large samples will give rise to small standard errors and significant values will arise from even small deviations from normality (Kirkwood and Sterne, 2003). Consequently, the shape of the distribution was assessed visually to identify departures from normality. With the exception of MVPA, all variables were considered to be normally distributed. A square root transformation successfully removed the positive skewness for the purpose of parametric analyses. Since one of the main outcomes was the metabolic syndrome, whereby participants were either classified with or without the condition, the distribution of variables was additionally examined by group. No further transformations were required.

3.7.2. Exposure and outcome variables and type of analysis

The exposure and outcome variables, type of analysis and potential covariates are described for each study hypothesis below.

H1. Physical activity is associated with HbA_{1c}

Exposure: Physical activity (continuous variable)

Outcome: HbA_{1c} (continuous variable)

Analysis: Unadjusted linear regression and adjusted linear regression

Covariates: Age (continuous), sex (nominal), BMI (continuous), diabetes medication (dichotomous)

H2. $VO_{2max\ pred}$ is associated with HbA_{1c}

Exposure: $VO_{2max\ pred}$ (continuous variable)

Outcome: HbA_{1c} (continuous variable)

Analysis: Unadjusted linear regression and adjusted linear regression

Covariates: Age (continuous), sex (nominal), BMI (continuous), diabetes medication (dichotomous)

H3. $VO_{2max.pred}$ modifies the association between physical activity and HbA_{1c}

Exposure: Interaction between $VO_{2max.pred}$ and physical activity (continuous variable)

Outcome: HbA_{1c} (continuous variable)

Analysis: Unadjusted linear regression and adjusted linear regression

Covariates: Age (continuous), sex (nominal), BMI (continuous), diabetes medication (dichotomous)

H4. Physical activity is associated with the metabolic syndrome

Exposure: Physical activity (continuous and dichotomous variables)

Outcome: Metabolic syndrome (dichotomous variable)

Analysis: Unadjusted logistic regression and adjusted logistic regression

Covariates: Age (continuous), sex (nominal)

H5. $VO_{2max.pred}$ is associated with the metabolic syndrome

Exposure: $VO_{2max\ pred}$ (continuous and dichotomous variables)

Outcome: Metabolic syndrome (dichotomous variable)

Analysis: Unadjusted logistic regression and adjusted logistic regression

Covariates: Age (continuous), sex (nominal), physical activity CPM (continuous)

H6. $VO_{2max.pred}$ modifies the association between physical activity and the metabolic syndrome

Exposure: Interaction between $VO_{2max.pred}$ and physical activity (continuous variable)

Outcome: Metabolic syndrome (dichotomous variable)

Analysis: Unadjusted logistic regression and adjusted logistic regression

Covariates: Age (continuous), sex (nominal)

3.7.3. Descriptive analyses

Descriptive data are expressed as means ± standard deviations or 95% confidence intervals, unless otherwise stated. Appropriate tables and graphs are presented in the results chapter to illustrate these data.

3.7.4. Statistical analyses

Associations and comparative analyses

Relations between continuous variables were examined using Pearson correlation coefficients when data were parametric and Spearman correlation coefficients when data were non-parametric. A number of tests were used to examine differences between exposure sub-groups. Continuous outcome data that adhered to parametric assumptions were examined using independent samples t-tests or analysis of variance (ANOVA), depending on whether there were two or more exposure groups. The Mann-Whitney U Test was chosen for non-parametric continuous outcome data. Associations between dichotomous/nominal exposures and outcomes were explored using the Chi Square Test. Within-group differences were analysed with paired samples t-tests.

Univariable analyses

After checking for evidence of collinearity, Pearson-product moment correlation coefficients and Spearman correlation coefficients were used to examine the relationship between two variables (see Appendix 15). Exposure and outcome variables were entered into linear regression models in their continuous form to examine associations.

Multivariable analyses

Exposure and outcome variables were entered into multivariable linear regression models in their continuous form to examine exposure effects, with adjustments made for confounders. Confounders were defined as covariates relating to both exposure and outcome variables, and included a priori covariates, such as age and BMI, and covariates identified through exploratory analyses, involving the examination of correlation coefficient tables (see Appendix 15).

Logistic analyses

Continuous exposure and binary outcome (metabolic syndrome status) variables were entered into logistic regression models to examine exposure effects, with adjustments made for confounders, as defined above.

Odds ratios were computed to examine the influence of physical activity or predicted VO_{2max} on the metabolic syndrome. When the exposure was categorical, odds were estimated relative to the lowest physical activity level or fitness level. The statistical significance of each regression parameter coefficient was evaluated using the Wald test.

Interaction analyses

In order to investigate an interaction effect between two exposure variables on an outcome variable, the exposure values were multiplied together to create an interaction variable that was entered into the regression model.

Interpretation and reporting of analyses

Regression coefficients are reported along with 95% confidence intervals and P values. A P value <0.05 was interpreted as statistically significant. Appropriate tables and graphs are presented to illustrate associations.

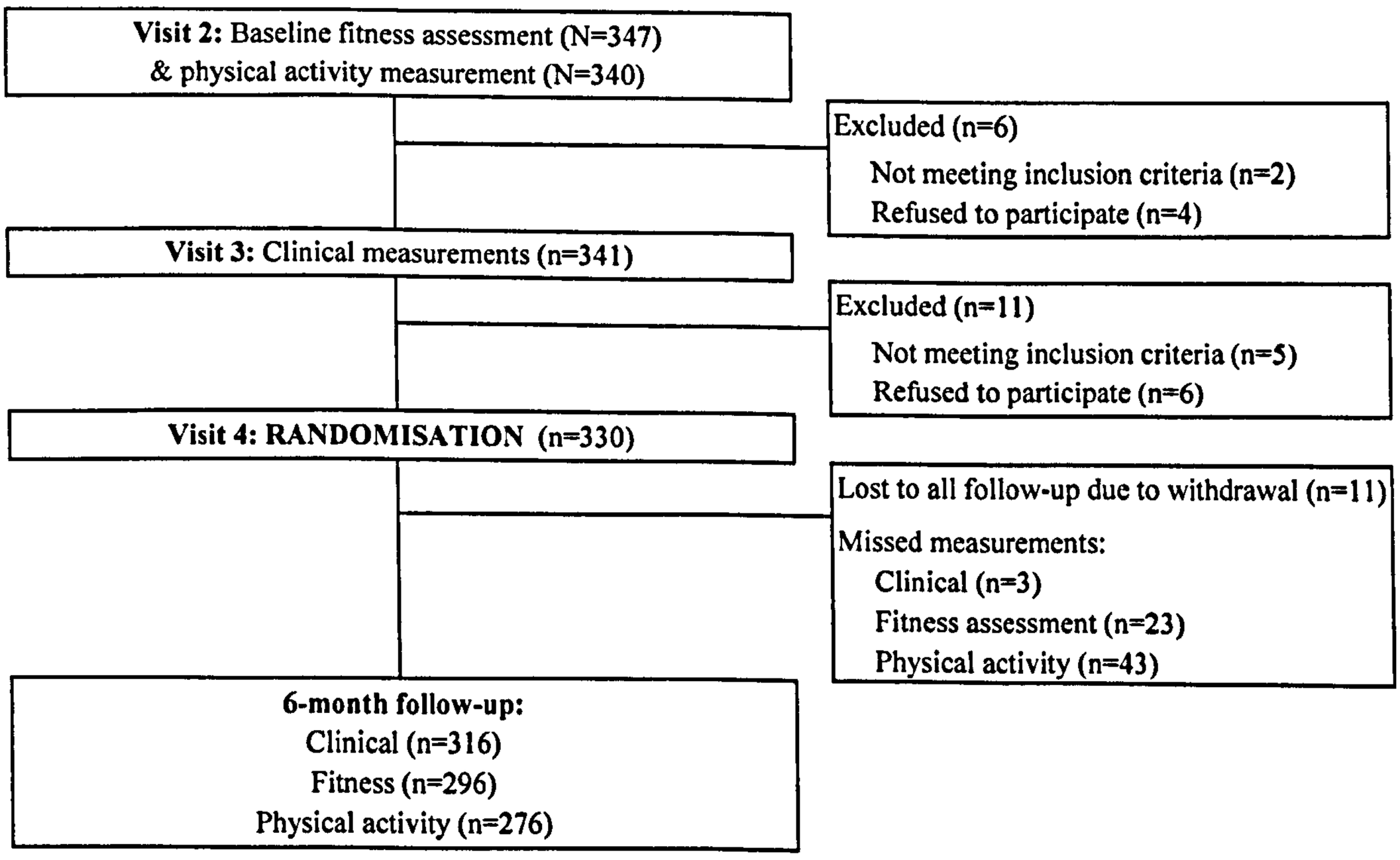
Chapter 4. Results

This chapter will present the main results of this PhD study. Recruitment and follow-up of participants will be described, followed by a description of the participants' characteristics. Physical activity and cardiorespiratory fitness levels in the study cohort will be covered in detail, since these are the main exposure variables under examination. Finally, the relationship between physical activity, cardiorespiratory fitness and metabolic and cardiovascular outcomes will be explored and presented.

4.1. Recruitment and follow-up

Recruitment to the study commenced in November 2005. At the time of analysing data presented in this thesis, 347 participants had undergone baseline assessment for the Early ACTID trial. Figure 4.1 illustrates the flow of participants from the first baseline assessment (Visit 2) to the six-month follow-up.

Figure 4.1. Flow of participants from baseline to six months



Seven individuals were found to be ineligible before randomisation. Of the 340 eligible individuals, ten decided not to participate in the study. Three-hundred and thirty participants were randomised to one of the three groups. Eleven participants (3.3%) withdrew in the first six months and did not undergo follow-up

assessment. At the six-month follow-up, 266 participants (80.6% of those randomised) underwent all clinical, cardiorespiratory fitness (CRF) and physical activity measures. Twenty-seven participants (8.2%) missed the physical activity assessment only, seven (2.1%) missed the CRF testing only, and 16 (4.8%) missed both the physical activity and CRF measures. Two participants (0.6%) failed to attend only the six-month clinical assessment, and one participant (0.3%) performed only the CRF test.

4.2. Participant characteristics and physiological outcomes

The characteristics of the study participants at baseline and six-months are summarised in Table 4.1a and 4.1b, respectively. Demographic data are shown for participants who met the study inclusion criteria and had undergone at least one of the following baseline measurements: 1) clinical, 2) fitness, or 3) physical activity. All participants had a BMI ≥24 kg/m^2. Forty-one percent (n=140) of participants were categorised as normal weight or overweight (BMI 20-29.9), 50% (n=169) as obese (BMI 30.0-39.9), and 9% (n=31) as morbidly obese (BMI ≥40.0).

A blood pressure measurement was obtained for 335 participants. Of these, according to the World Health Organization guidelines (WHO, 1999), 17% (n=57) had optimal blood pressure (<120/80mmHg), 17% (n=58) had normal blood pressure (120-129/80-84mmHg), 30% (n=103) had high-normal blood pressure (130-139/85-89mmHg) and 34% (n=117) had hypertension (140-179/90-109mmHg). No participants were categorised as having severe hypertension (>180/110mmHg), as this was one of the Early ACTID Study exclusion criteria. At the time of entering the study, 52% (n=176) of participants were prescribed anti-hypertensive medications.

Baseline HbA_{1c} values were obtained for 335 participants. In relation to the NICE classification of HbA_{1c} values, almost one quarter of the sample (n=80) had optimal HbA_{1c} values, which were less than 6%. Twenty-nine percent (n=97) had good control (6-6.49%), 32% (n=108) had acceptable control (6.5-7.49%), and 15% (n=50) had poor glycaemic control, with values ≥7.5%. One third of participants (n=110) were prescribed diabetes medications. Just 28.8% of participants (n=98) were not prescribed medication for their diabetes, blood pressure or blood lipids.

Table 4.1a. Baseline characteristics of participants in the Early ACTID Study

	ALL		MEN		WOMEN		GENDER DIFFERENCE		
CHARACTERISTIC	N	Mean ± SD	N	Mean ± SD	N	Mean ± SD	P value	95% Confidence interval	
DEMOGRAPHICS									
Age (years)	340	59.30 ± 10.38	207	60.00 ± 9.98	133	58.23 ± 10.93	0.13	-4.00	0.52
Height (meters)	340	1.69 ± 0.09	207	1.75 ± 0.07	133	1.61 ± 0.06	**<0.01**	-0.15	-0.12
Weight (kilograms)	340	91.65 ± 16.96	207	94.02 ± 14.49	133	87.95 ± 19.71	**0.03**	-9.63	-2.07
Body Mass Index (kg/m^2)	340	31.99 ± 5.62	207	30.81 ± 4.40	133	33.82 ± 6.73	**<0.01**	1.72	4.32
PHYSIOLOGICAL									
Systolic blood pressure (mmHg)	335	134.31 ± 15.07	205	136.18 ± 14.52	130	131.35 ± 15.49	**0.05**	-8.03	-1.45
Diastolic blood pressure (mmHg)	335	78.90 ± 8.38	205	79.06 ± 8.20	130	78.66 ± 8.66	0.67	-2.25	1.44
BIOCHEMICAL									
HbA_{1c} (%)	335	6.61 ± 1.00	206	6.58 ± 0.97	129	6.66 ± 1.04	0.66	-0.18	0.28
Cholesterol (mmol/l)	336	4.38 ± 0.92	206	4.27 ± 0.92	130	4.55 ± 0.89	**<0.01**	0.07	0.47
Triglycerides (mmol/l)	336	1.69 ± 1.01	206	1.73 ± 1.05	130	1.62 ± 0.93	0.31	-0.34	0.11
HDL cholesterol (mmol/l)	336	1.32 ± 0.34	206	1.25 ± 0.29	130	1.44 ± 0.37	**<0.01**	0.12	0.27
LDL cholesterol (mmol/l)	328	2.31 ± 0.79	201	2.26 ± 0.8	127	2.39 ± 0.78	0.16	-0.05	0.30
Glucose (mmol/l)	334	7.36 ± 1.54	205	7.35 ± 1.43	129	7.37 ± 1.70	0.92	-0.32	0.36
Insulin (mU/L)	332	16.86 ± 11.26	204	16.53 ± 11.4	128	17.39 ± 11.06	0.50	-1.64	3.36
HOMA	332	5.56 ± 4.17	204	5.40 ± 4.10	128	5.83 ± 4.29	0.37	-0.50	1.35

Data are means ± SD; HbA_{1c}, Glycated haemoglobin; HDL, high-density lipoprotein; LDL low-density lipoprotein

Table 4.1b. Six-month characteristics of participants in the Early ACTID Study

	ALL		MEN		WOMEN		GENDER DIFFERENCE		
CHARACTERISTIC	N	Mean ± SD	N	Mean ± SD	N	Mean ± SD	P value	95% Confidence interval	
DEMOGRAPHICS									
Age (years)	317	60.22 ± 10.1	195	60.99 ± 9.74	122	59.02 ± 10.59	0.18	-4.00	0.75
Height (meters)	317	1.69 ± 0.09	195	1.75 ± 0.07	122	1.61 ± 0.07	**<0.01**	-0.15	-0.12
Weight (kilograms)	317	89.49 ± 17.33	195	92.17 ± 15.32	122	85.20 ± 19.43	**<0.01**	-11.06	-2.89
Body Mass Index (kg/m^2)	317	31.17 ± 5.64	195	30.20 ± 4.68	122	32.72 ± 6.63	**<0.01**	1.17	3.89
PHYSIOLOGICAL									
Systolic blood pressure (mmHg)	335	134.31 ± 15.07	192	134.58 ± 14.18	120	132.19 ± 14.1	0.15	-5.63	0.85
Diastolic blood pressure (mmHg)	335	78.90 ± 8.38	192	78.95 ± 8.28	120	78.45 ± 8.06	0.60	-2.38	1.38
BIOCHEMICAL									
HbA_{1c} (%)	314	6.65 ± 1.01	194	6.68 ± 1.06	120	6.60 ± 0.94	0.48	-0.32	0.15
Cholesterol (mmol/l)	312	4.31 ± 0.84	193	4.19 ± 0.88	119	4.50 ± 0.74	**<0.01**	0.12	0.50
Triglycerides (mmol/l)	312	1.60 ± 0.91	193	1.66 ± 1.02	119	1.49 ± 0.68	0.09	-0.39	0.03
HDL cholesterol (mmol/l)	312	1.33 ± 0.33	193	1.23 ± 0.29	119	1.48 ± 0.34	**<0.01**	0.18	0.32
LDL cholesterol (mmol/l)	310	2.26 ± 0.74	191	2.21 ± 0.78	119	2.34 ± 0.66	0.12	-0.04	0.30
Glucose (mmol/l)	312	7.34 ± 1.54	193	7.46 ± 1.58	119	7.15 ± 1.46	0.92	-0.65	0.05
Insulin (mU/L)	312	16.08 ± 10.42	193	16.20 ± 11.05	119	15.87 ± 9.37	0.79	-2.73	2.06
HOMA	312	5.37 ± 4.05	193	5.52 ± 4.42	119	5.13 ± 3.37	0.38	-1.32	0.54

Data are means ± S; HbA_{1c}, Glycated haemoglobin; HDL, high-density lipoprotein; LDL low-density lipoprotein

The prevalence of each individual component of the IDF criteria for the classification of the metabolic syndrome (International Diabetes Federation, 2006) was examined in the study cohort. These components include: 1) a diagnosis of diabetes, 2) obesity (BMI ≥30kg/m^2), 3) triglycerides >1.7mmol/l or the treatment for dyslipidaemia, 4) HDL-cholesterol <1.1mmol/l in men and <1.3mmol/l in women, or treatment of dyslipidaemia, and 5) systolic blood pressure >130mmHg or diastolic blood pressure >85mmHg, or treatment of hypertension. Figure 4.2 shows the percentage of participants meeting the criteria for each individual component of the metabolic syndrome, while Figure 4.3 shows the percentage of participants by the number of components that meet the criteria.

Figure 4.2. Percentage of participants meeting individual components of the IDF metabolic syndrome criteria

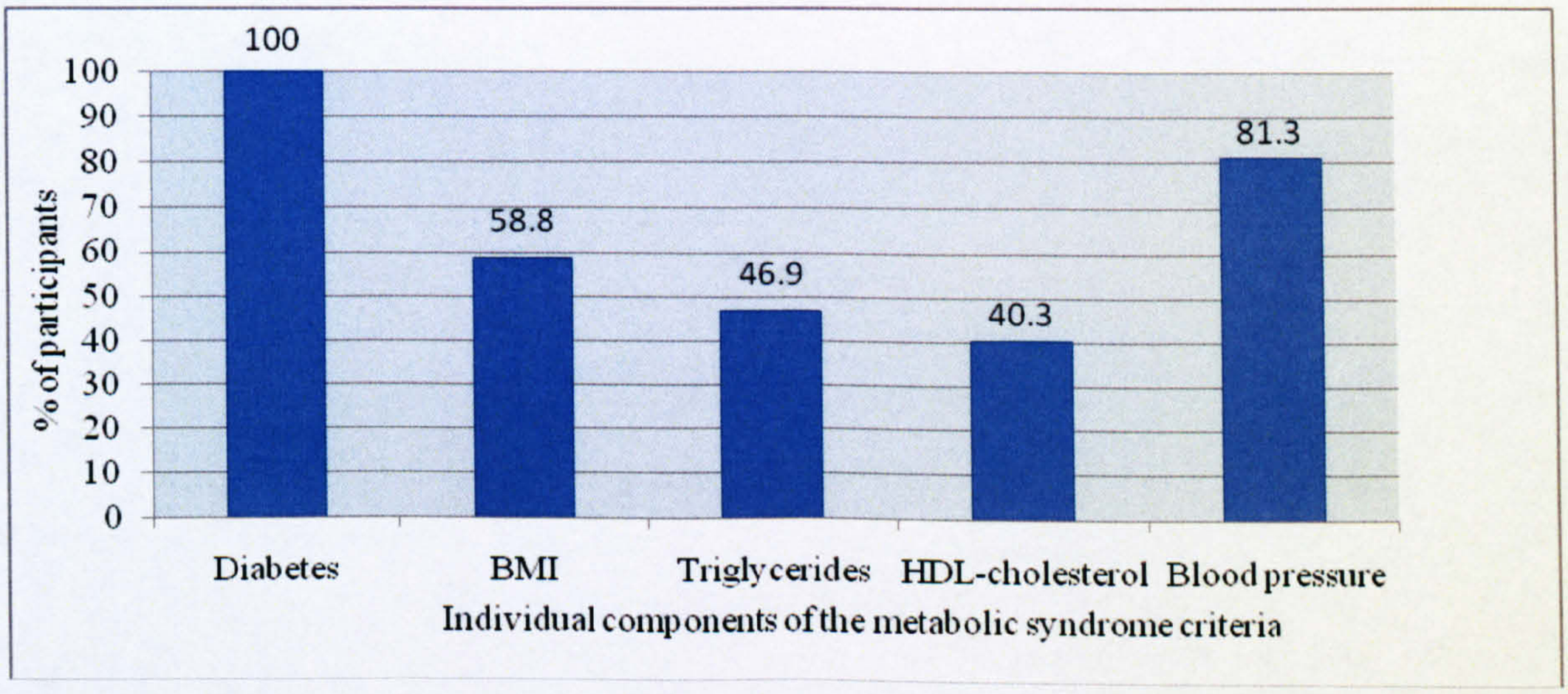
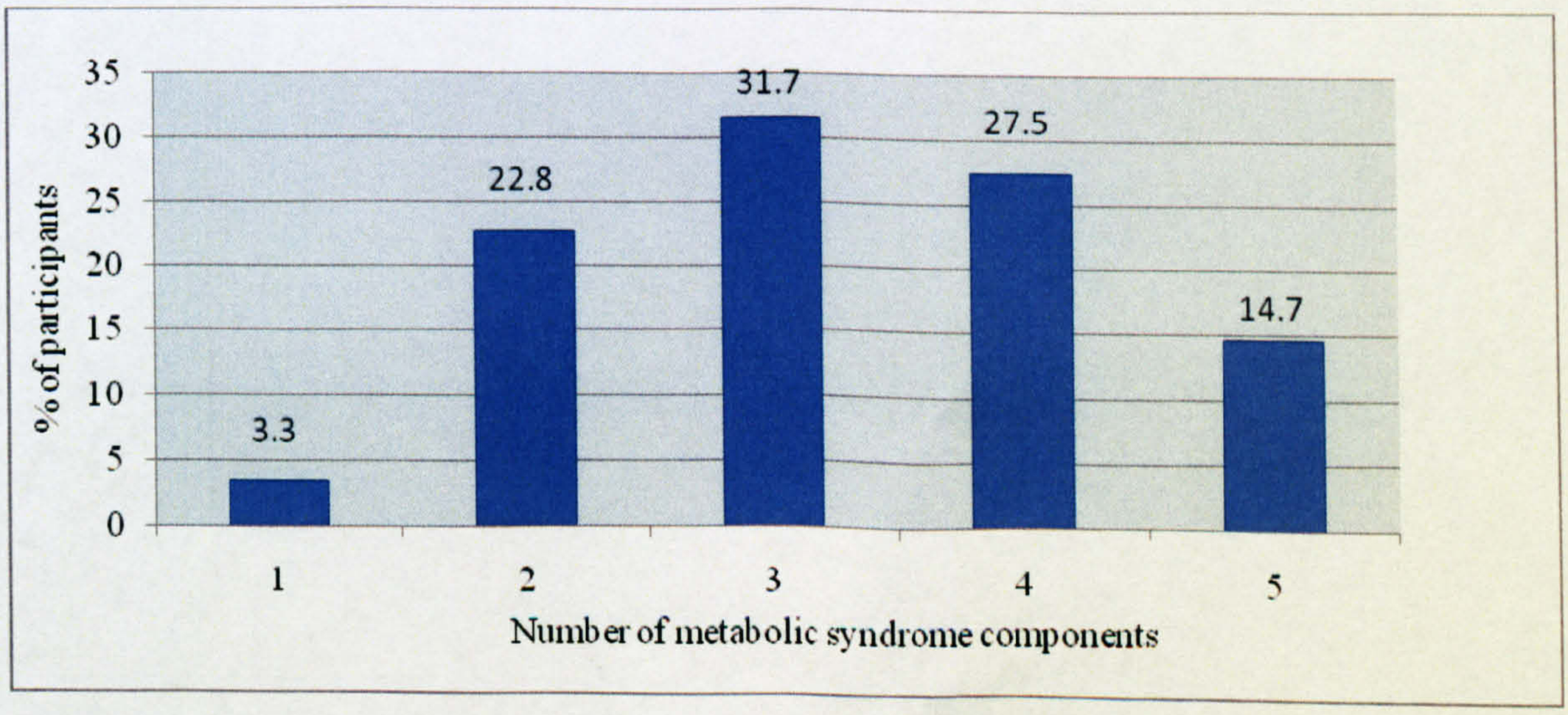


Figure 4.3. Percentage of participants by the total number of components meeting the IDF metabolic syndrome criteria



A total of 336 participants had sufficient data to determine the prevalence of the metabolic syndrome. A BMI ≥30, or a waist circumference ≥94cm for men and ≥80cm for women, is an essential component of the IDF criteria, and individuals are required to have at least two other factors for the classification of the metabolic syndrome. One of the additional IDF factors includes a fasting plasma glucose ≥5.6mmol/l or diagnosed T2D. Since all of the participants in this study met this criterion, just one other factor in addition to a BMI ≥30 was necessary. Fifty-four percent (n=151) of participants met the full metabolic syndrome criteria. The prevalence of the condition was higher in women than men (60% vs. 50%, χ^2 (1)=3.58, P=0.07), although this difference reached only borderline significance. Of those participants with a BMI ≥30, 92% were classified with the metabolic syndrome. Of these, 35% met just one additional criterion, 35% met two additional criteria, and 27% met all three additional criteria, and thus, met all individual criteria of the IDF metabolic syndrome definition. Of those participants with a BMI <30, 17% did not have any of the additional metabolic syndrome components, 39% met one criterion, 25% met two criteria, and 19% had all three additional criteria.

Table 4.2 shows participant characteristics of those classified with and without the metabolic syndrome at baseline. Participants meeting the criteria were significantly heavier, and they had higher BMIs, higher fasting insulin levels and higher HOMA scores compared to those without the metabolic syndrome. There were no significant between-group differences for the other participant characteristics reported in Table 4.2. Although blood pressure did not differ significantly between the two groups, the proportion of participants prescribed antihypertensive medication was higher in the group with the metabolic syndrome compared to the group without the metabolic syndrome (59.1% vs. 44.5%, χ^2 (1)=7.14, P=0.009). The proportion of participants prescribed diabetes and lipid medication did not differ between groups. The relationship between physical activity, cardiorespiratory fitness and the metabolic syndrome will be described in section 4.5.

At six months, 313 participants had sufficient data to determine the prevalence of the metabolic syndrome. Of these, 47% (n=147) met the metabolic syndrome criteria. Among those participants with sufficient data to determine the presence of the metabolic syndrome at both baseline and six months (n=312), chi square analyses revealed that significantly fewer participants met the metabolic syndrome criteria at six months than at baseline (52.9% vs. 47.1%, χ^2 (1)=150.07, P<0.001). The difference in the metabolic syndrome prevalence between women and men was slightly more pronounced at six months (54.5% (n=66) vs. 42.2% (n=81), χ^2 (1)=4.55, P=0.02).

Table 4.2. Baseline characteristics by metabolic syndrome status of participants in the Early ACTID Study

CHARACTERISTIC	METABOLIC SYNDROME (mean ± SD)		BETWEEN-GROUP DIFFERENCE		
	No	Yes	P value	95% Confidence interval	
DEMOGRAPHICS					
Age (years)	59.89 ± 10.25	58.74 ± 10.42	0.309	-1.07	3.38
Height (meters)	1.70 ± 0.10	1.69 ± 0.09	0.087	0.00	0.38
Weight (kilograms)	81.78 ± 11.08	100.32 ± 16.16	**<0.001**	-21.79	-15.90
Body Mass Index (kg/m^2)*	28.02 ± 2.32	35.37 ± 5.39	**<0.001**	-8.22	-6.48
PHYSIOLOGICAL					
Systolic blood pressure (mmHg)†	133.99 ± 16.04	134.61 ± 14.23	0.713	-3.91	2.68
Diastolic blood pressure (mmHg)†	78.48 ± 8.27	79.28 ± 8.51	0.388	-2.62	1.02
BIOCHEMICAL					
HbA_{1c} (%)	6.65 ± 1.04	6.56 ± 0.93	0.432	-0.13	0.30
Cholesterol (mmol/l)	4.39 ± 0.92	4.39 ± 0.91	0.999	-0.20	0.20
Triglycerides (mmol/l)†	1.60 ± 0.88	1.77 ± 1.10	0.127	-0.39	0.05
HDL cholesterol (mmol/l)†	1.35 ± 0.33	1.30 ± 0.34	0.124	-0.02	0.13
LDL cholesterol (mmol/l)	2.31 ± 0.82	2.31 ± 0.77	0.938	-0.18	0.17
Glucose (mmol/l)	7.40 ± 1.53	7.33 ± 1.55	0.647	-0.26	0.41
Insulin (mU/L)	12.21 ± 5.64	20.86 ± 13.25	**<0.001**	-10.81	-6.50
HOMA	4.07 ± 2.26	6.86 ± 4.97	**<0.001**	-3.61	-1.97

HbA_{1c}, glycated haemoglobin; HDL, high-density lipoprotein; LDL low-density lipoprotein; * BMI ≥30 is an essential component of the IDF definition of the metabolic syndrome; † Additional components of IDF metabolic syndrome definition, of which at least one, in addition to BMI ≥30, is required in people with a diagnosis of T2D.

4.3. Physical activity

4.3.1. Compliance with the measurement protocol

Baseline measurement

At the time of performing analyses, an ActiGraph had been given to 340 participants undergoing baseline assessments. Five (1.5%) monitors were not returned by participants. Of the 335 returned ActiGraphs, seven (2.1%) could not be downloaded due to a technical fault and seven (2.1%) had no registered days of recording, suggesting the monitor had not been worn. Accelerometer data were therefore obtained from 321 participants (198 men, 123 women) at baseline.

Two-hundred and sixty-two participants (81.6%) wore the accelerometer for at least ten registered hours on seven days, as requested, and 43 (13.4%) recorded six days of measurement. Recent reports on

accelerometry in free-living individuals indicate that ten or more hours of recording on at least three week days and one weekend day of measurement provide the most reliable estimate of physical activity (Corder et al., 2007). As such, participants providing baseline ActiGraph data were categorised according to the number of days where at least ten registered hours of recording had been obtained. The criteria of having at least three valid weekdays and one weekend day were met by 314 participants (97.8%). No significant difference in mean daily monitor wear, physical activity volume or MVPA was found between the two groups. Therefore, all participants providing accelerometer data are included in the analyses presented in this thesis. Baseline physical activity data are shown in Table 4.3a.

Six-month measurement

Three-hundred and nineteen participants remained in the study at six months. Of these, accelerometer data were obtained for 276 participants (86.5%). Eleven (3.2%) ActiGraphs were not returned by participants, three (0.9%) could not be downloaded due to a technical fault, and six (1.8%) had no registered days of recording. Twenty-three participants (7.2%) were not provided with an ActiGraph at six months, either because of prolonged ill-health or injury, or because of non-attendance at their six-month fitness test.

One-hundred and ninety-one participants (69.2%) wore the accelerometer for at least ten registered hours on seven days, and 49 (17.8%) recorded six days of measurement. Table 4.3b shows the six-month physical activity data. A total of 164 participants provided seven valid days of accelerometry data at both baseline and six months.

4.3.2. Levels of physical activity

Baseline physical activity

A one-way repeated measures test revealed there were no significant differences in physical activity between individual weekdays (CPM: $F(3.7, 951.1)=.430$, P=0.78; MVPA: $F(3.8, 111.8)=1.21$, P=0.31). Similarly, a paired t-test showed no significant difference between the two weekend days ($t(278)=1.61$, P=0.11).. As such, data for these two periods were combined as mean weekday and mean weekend day values. Physical activity volume, as determined by mean counts per minute (CPM), was 4% lower during weekend days compared with week days ($t(315)=1.933$, P=0.05). Differences between the two periods were more pronounced for time spent in MVPA, with participants spending 15% less time performing this intensity of activity during weekend days than week days ($t(315)=.991$, P<0.001).

Table 4.3a. Baseline physical activity data collected from participants in the Early ACTID Study

	ALL		MEN		WOMEN		GENDER DIFFERENCE	
OUTCOMES	N	Mean ± SD	N	Mean ± SD	N	Mean ± SD	P value	95% Confidence interval
Total measurement days	321	6.74 ± 0.66	198	6.76 ± 0.61	123	6.71 ± 0.74	0.51	-0.20 0.10
Total measurement hours	321	106.87 ± 14.24	198	107.73 ± 14.15	123	105.48 ± 14.33	0.17	-5.47 0.96
Hours day^{-1}	321	15.84 ± 1.29	198	15.91 ± 1.36	123	15.73 ± 1.15	0.21	-0.47 0.11
Counts week^{-1}	267	1612420.00 ± 646463.00	167	1718503.00 ± 619723.00	99	1433760.00 ± 661905.00	**<0.01**	-444308.00 -125178.00
Counts minute^{-1}	321	243.12 ± 97.17	198	251.79 ± 92.96	123	229.16 ± 102.43	**0.04**	-44.47 -0.79
Counts minute^{-1}·wk·day^{1}	321	245.48 ± 101.47	198	254.04 ± 99.55	123	231.70 ± 103.41	0.06	-45.16 0.49
Counts minute^{-1}·we·day^{1}	316	234.31 ± 112.89	195	244.04 ± 109.41	121	218.62 ± 117.05	0.05	-51.01 0.17
MVPA total minutes·week^{-1}[a]	267	150.68 ± 119.24	163	166.91 ± 121.25	99	122.46 ± 112.84	**<0.01**	-74.088 -14.799
MVPA minutes·day^{-1}	321	21.57 ± 17.62	198	23.33 ± 17.64	123	18.74 ± 17.29	**0.02**	-8.54 -0.64
MVPA minutes^{-1}·wk·day^{1}	321	22.47 ± 19.1	198	24.16 ± 19.5	123	19.76 ± 18.2	**0.05**	-8.70 -0.11
MVPA minutes^{-1}·we·day^{1}	316	18.83 ± 19.31	195	21.03 ± 20.09	121	15.29 ± 17.48	**<0.01**	-9.96 -1.52

Data are means ± SD; P value derived from independent t-test; * P value derived from Mann-Whitney U test; MVPA, moderate to vigorous physical activity; [a], Includes only participants with 7 days of measurement

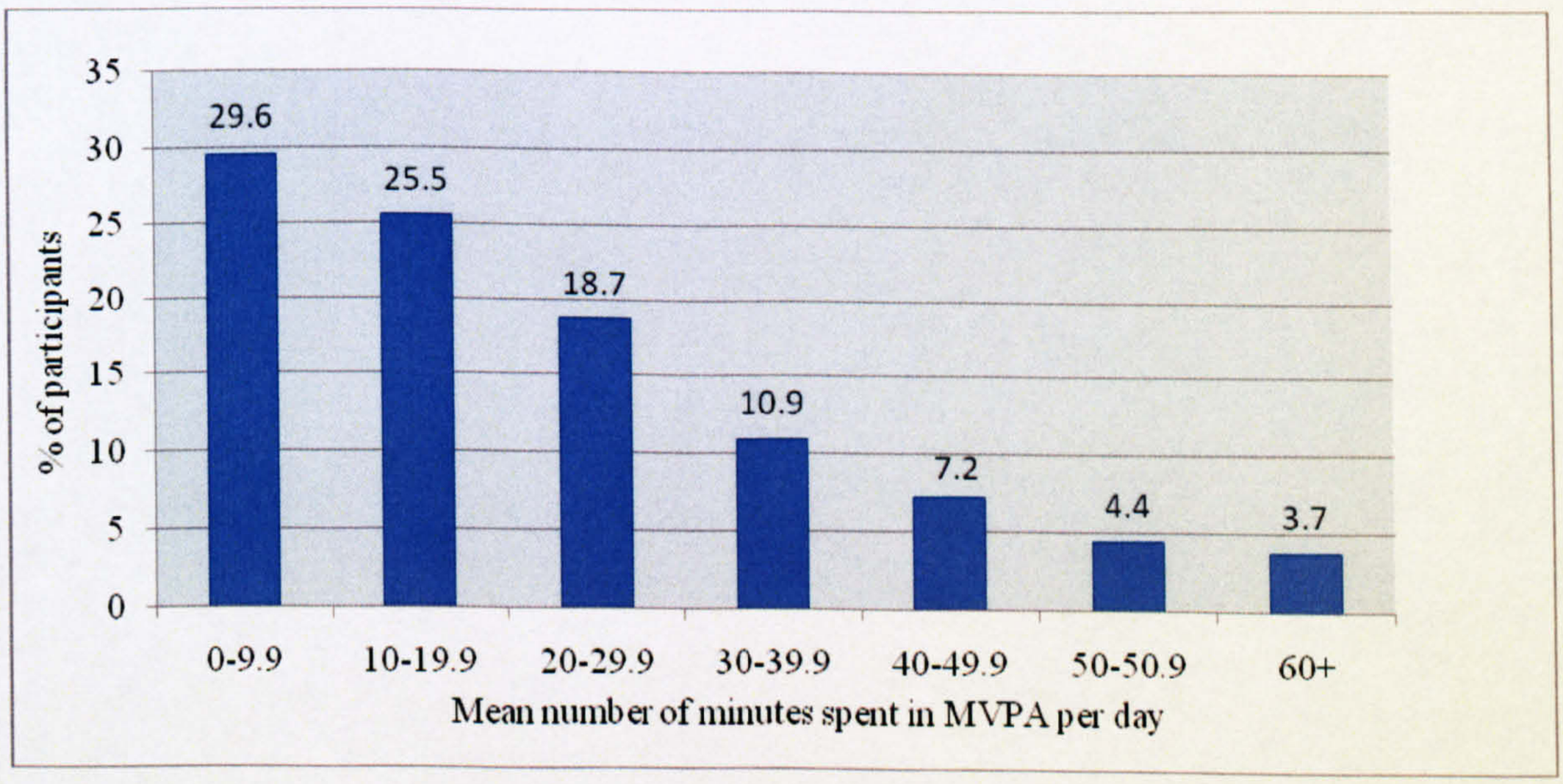
Table 4.3b. Six-month physical activity data collected from participants in the Early ACTID Study

	ALL		MEN		WOMEN		GENDER DIFFERENCE	
OUTCOMES	N	Mean ± SD	N	Mean ± SD	N	Mean ± SD	P value	95% Confidence interval
Total measurement days	276	6.46 ± 1.01	176	6.53 ± 0.97	100	6.35 ± 1.06	0.16	-0.43 0.07
Total measurement hours	276	100.46 ± 19.77	176	102.39 ± 19.62	100	97.06 ± 19.67	**0.03**	-10.17 -0.48
Hours day^{-1}	276	15.46 ± 1.4	176	15.60 ± 1.41	100	15.21 ± 1.34	**0.03**	-0.73 -0.05
Counts week^{-1}	191	1634272.00 ± 729710.00	129	1676519.00 ± 711619.00	62	1546371.00 ± 764390.00	0.25	-352393.00 92097.58
Counts minute^{-1}	276	245.40 ± 111.32	176	255.32 ± 116.38	100	227.93 ± 100.00	**0.05**	-54.69 -0.09
Counts minute^{-1}·wk·day^{1}	276	245.00 ± 112.56	176	254.83 ± 118.85	100	227.68 ± 98.74	0.05	-54.76 0.46
Counts minute^{-1}·we·day^{1}	265	243.76 ± 133.26	168	253.07 ± 131.86	97	227.62 ± 134.82	0.13	-58.83 7.94
MVPA total minutes·week^{-1}[a]	276	172.57 ± 131.43	129	184.09 ± 128.76	62	148.61 ± 134.73	0.08	-75.32 4.37
MVPA minutes·day^{-1}	276	23.62 ± 19.15	176	26.03 ± 19.59	100	19.40 ± 17.65	**<0.01**	-11.29 -1.97
MVPA minutes^{-1}·wk·day^{1}	276	23.84 ± 19.48	176	26.05 ± 20.24	100	19.94 ± 17.51	**0.01**	-10.87 -1.36
MVPA minutes^{-1}·we·day^{1}	265	22.52 ± 24.89	168	25.33 ± 24.54	97	17.64 ± 24.86	**0.02**	-13.89 -1.50

Data are means ± SD; P value derived from independent t-test; * P value derived from Mann-Whitney U test; MVPA, moderate to vigorous physical activity; [a], Includes only participants with 7 days of measurement

Figure 4.4 shows the percentage of participants accumulating different amounts of MVPA per day at baseline. Of those participants with seven days of recording (163 men, 99 women), 81 (49.7%) men and 29 (29.3%) women accumulated at least 150 minutes of moderate to vigorous physical activity (MVPA) during the recording period, which is the minimum weekly total recommended in national guidelines for physical activity (Department of Health, 2004). When the data were analysed to determine the number accumulating ≥30 minutes on at least five days per week, just 26 (16.0%) men and 11 (11.1%) women achieved this level of activity. Seventeen (10.4%) men and 14 (14.1%) women accumulated <30 minutes of MVPA during the 7-day recording period, which is the amount considered sedentary or inactive (Department of Health, 2004). Of these, six men and three women did not have any registered minutes of MVPA. Of those participants providing at least one valid accelerometer measurement day (n=321), 60 (30.3%) men and 24 (19.5%) women recorded a mean of at least 30 minutes of MVPA accumulated per day. Nine (4.5%) men and six (4.9%) women had no registered minutes of MVPA.

Figure 4.4. Percentage of participants accumulating different amounts of MVPA per day at baseline, as determined by accelerometry



Six-month physical activity

At six months, differences between weekday and weekend day physical activity levels were only significant for time spent in MVPA (P=0.003). Differences in physical activity volume were not significant. A total of 48.2% (51.9% men, 40.3% women) of participants providing seven days of accelerometer data accumulated at least 150 minutes of MVPA. Four participants (2.1%) did not register

any MVPA minutes during the seven days of measurement. Eighty-four (30.7%) participants (37.1% men and 19.2% women) with at least one valid measurement day accumulated a mean daily average of 30 minutes of MVPA. When only those participants providing data at both baseline and six months were examined, the proportions accumulating 150 minutes per week or 30 minutes per day were fairly similar (47.0 vs. 48.2% and 26.8 vs. 30.9%, respectively).

4.3.3. Physical activity by demographic characteristics

Significant independent demographic predictors of physical activity volume (CPM) were age (β=-.283, t(319)=-5.26, adjusted R^2=.077, P<0.001), BMI (β=-.203, t(319)=-3.709, adjusted R^2=.038, P<0.001) and gender (β=.113, t(319)=2.038, adjusted R^2=.010, P=0.042). Predictors of time spent in activity of at least moderate intensity were BMI (β=-.074, t(319)=-3.750, adjusted R^2=.040, P<0.001), age (β=-.029, t(319)=-2.788, adjusted R^2=.021, P=0.006) and gender (β=.549, t(319)=2.471, adjusted R^2=.016, P=0.014). There appeared to be an age-BMI interaction for both CPM (β=-.099, t(319)=-7.713, adjusted R^2=.155, P<0.001) and MVPA (β=-.002, t(319)=-5.749, adjusted R^2=.091, P<0.001).

Gender

Gender differences in levels of physical activity are shown in Table 4.3a at baseline and 4.3b at six months. Briefly, at baseline women were 9% less active than men (t(319)=-2.038 CPM, P=0.04) and spent 20% less time in MVPA (t(319)=-2.471 mean minutes·day^{-1}, P=0.01). These gender differences were slightly more pronounced at six months (11%, P=0.05 and 25%, P=0.002, respectively).

Age

There was a moderate inverse association between age and physical activity volume, as determined by mean accelerometer counts per minute (r=-.283, P<0.001), and time spent in MVPA (r=-.154, P=0.006). Associations between age and volume and intensity of physical activity were slightly weaker at six months (r=-.194, P=0.001 and r=-.111, P=0.07, respectively). When participants were divided into three equal age groups, corresponding to 31-54 years (mean 47 years), 55-65 years (mean 60 years) and 65-81 years (mean 70 years), mean CPM were 275.7 ± 89.8, 244.8 ± 98.4 and 208.9 ± 92.1, and mean daily MVPA minutes were 24.6 ± 17.2, 21.0 ± 17.6 and 19.1 ± 17.8, respectively. An ANOVA test revealed significant between-group differences in physical activity volume (F(2,318)=13.71, P<0.001) and time spent in MVPA (F(2,318)=3.16, P=0.04). As mentioned above, there was an interaction between age and BMI.

Examination of the associations by BMI category revealed that the inverse association between age and physical activity was much stronger among morbidly obese (BMI ≥40kg/m^2) participants (CPM, r=-.629; MVPA, r=-.734, P<0.001) than obese (BMI 30.00-39.99kg/m^2) (CPM, r=-.245, P=0.002; MVPA, r=-.167, P=0.03) and overweight (BMI 25.00-29.99kg/m^2) participants (CPM, r=-.369, P<0.001; MVPA, r=-.112 (NS)).

BMI status

Differences in physical activity between overweight, obese and morbidly obese BMI groups were examined using a one-way ANOVA test. There were significant differences in mean weekly CPM between BMI groups (F(2,318)=5.48, P=0.005), with post-hoc Bonferroni analyses showing the greatest difference between the overweight (M=258.30 ± 95.21 CPM) and morbidly obese groups (M=192.96 ± 87.95 CPM) (P=0.004, 95% CI 16.59 to 114.09). Differences between the overweight and obese groups (M=239.23 ± 97.53 CPM) were non significant. Differences in CPM were more pronounced at the weekend (F(2,315)=9.17, P<0.001).

There was also a significant difference between BMI groups in time spent in MVPA (F(2,318)=5.67, P=0.009, with post-hoc analyses showing that the morbidly obese group accumulated fewer minutes of MVPA per day than the overweight groups (M=13.88 ± 14.88 vs. 24.48 ± 17.73, P=0.013). Differences in MVPA were also more pronounced at the weekend, with the overweight group spending significantly more time in MVPA (M=23.60 ± 20.56) than both the obese (M=16.69 ± 18.51, P=0.006) and morbidly obese groups (M=8.17 ± 8.63, P<0.001). There were no other significant differences in physical activity CPM or minutes of MVPA between BMI groups. A two-way ANOVA revealed no interaction between gender and BMI in relation to physical activity.

The number of participants meeting the physical activity recommendation of accumulating 30 minutes of moderate intensity activity on at least five days per week was also examined by BMI status. The accelerometer counts indicated that 21.7% (n=25) of overweight, 9.6% of (n=12) of obese, and 0% of morbidly obese participants accumulated these recommended levels of activity over the 7-day recording period. The difference between groups was statistically significant (χ^2 (2)=11.23, P=0.004).

4.3.4. Physical activity by study group assignment

There was no significant difference between baseline and six-month physical activity volume or times spent in MVPA when the Early ACTID Study cohort was examined as one group. In order to assess the feasibility of increasing levels of physical activity in a group of adults with recently diagnosed T2D, mean six-month activity levels of those randomised to the *diet plus exercise* group were compared to mean levels of those allocated *non-exercise* (*diet only* and *usual care*) groups. Differences within and between groups were examined using dependent and independent t-tests, respectively. Although cross-sectional differences between groups were not significant at either baseline or six-months, within-group six-month changes in CPM and MVPA were statistically significant between groups. These differences are shown in Table 4.4. Between baseline and six months, mean CPM increased by 11.1% (P=0.02) and time spent in MVPA increased by 25.34% (P=0.001) within the *diet plus exercise* group. Within the non-exercise group, mean CPM decreased by 3% and time spent in MVPA by 1.5%. These changes were non-significant.

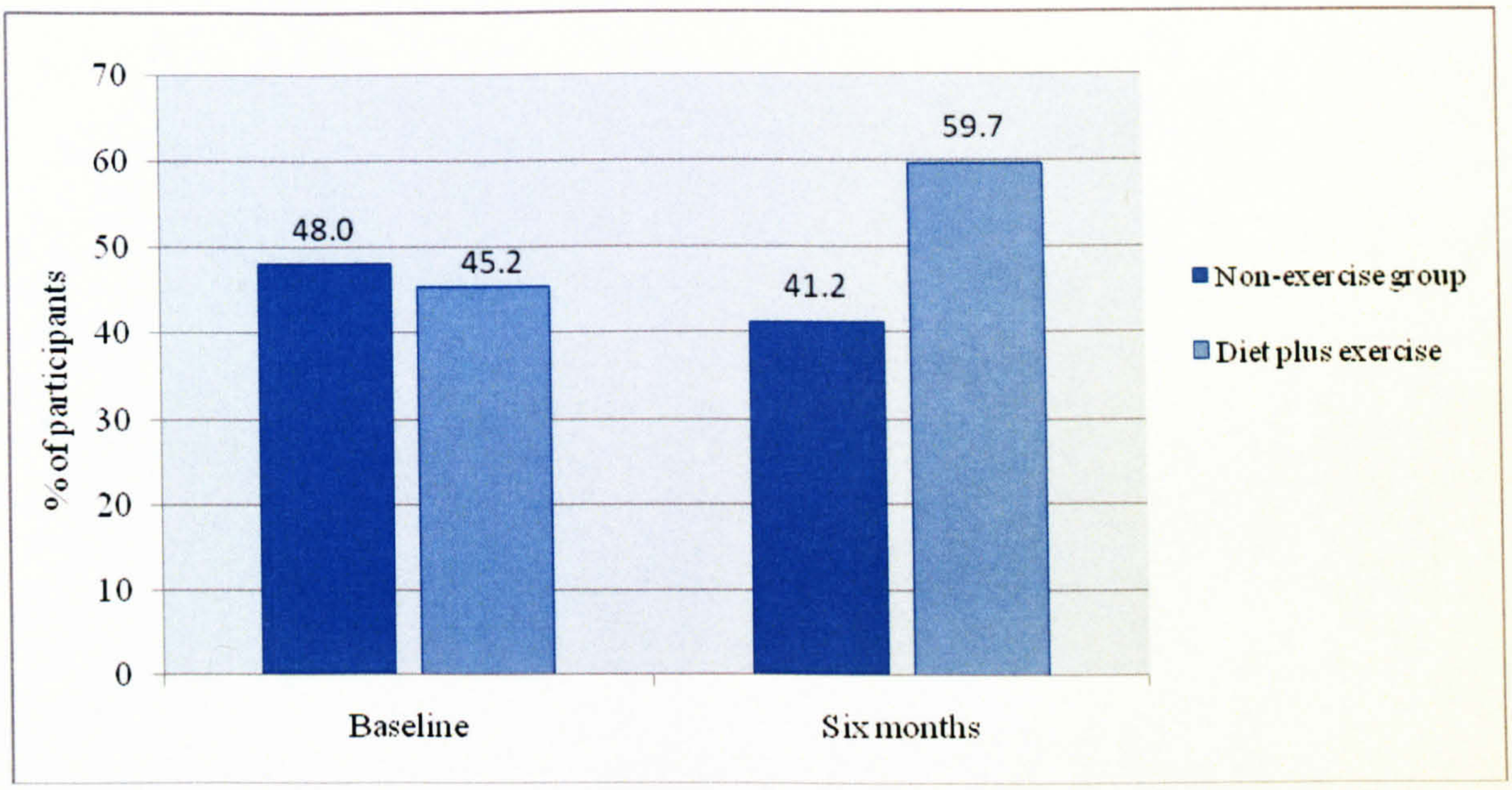
Table 4.4. Within-group change in physical activity from baseline to six months among participants in the Early ACTID Study

	NON-EXERCISE GROUP		DIET + EXERCISE GROUP		BETWEEN-GROUP DIFFERENCE		
PHYSICAL ACTIVITY OUTCOME	n	Mean ± SD	n	Mean ± SD	P value	95% Confidence interval	
Counts minute^{-1}	169	-7.5 ± 81.1	96	25.3 ± 79.7**	**0.002**	12.6	53.1
Counts minute^{-1}·wk·day^{-1}	169	-7.7 ± 79.5	96	20.1 ± 79.7*	**0.007**	7.8	47.9
Counts minute^{-1}·we ·day^{-1}	157	-9.6 ± 132.7	94	37.1 ± 118.1**	**0.005**	13.9	79.3
MVPA minutes^{-1}·day^{-1}	169	-0.4 ± 15.3	96	5.1 ± 14.0**	**0.005**	1.7	9.2
MVPA minutes^{-1}·wk·day^{-1}	169	-0.6 ± 16.2	96	3.9 ± 15.6*	**0.031**	0.4	8.5
MVPA minutes^{-1}·we·day^{-1}	157	-1.0 ± 25.9	94	7.7 ± 20.3**	**0.006**	2.5	14.8

* Significant within-group difference P<0.05; ** P<0.01

Figure 4.5 shows the percentage of *non-exercise* group and *diet plus exercise* group participants who accumulated 150 minutes of MVPA at baseline and six months. Only data from participants providing seven days of accelerometry at both time points are presented (n=191). At baseline, there was no significant difference between the groups; however, at six months a significantly greater proportion of participants randomised to the *diet plus exercise group* were accumulating the recommended 150 minutes compared to the *non-exercise* group (χ^2 (1)=6.18, P=0.017).

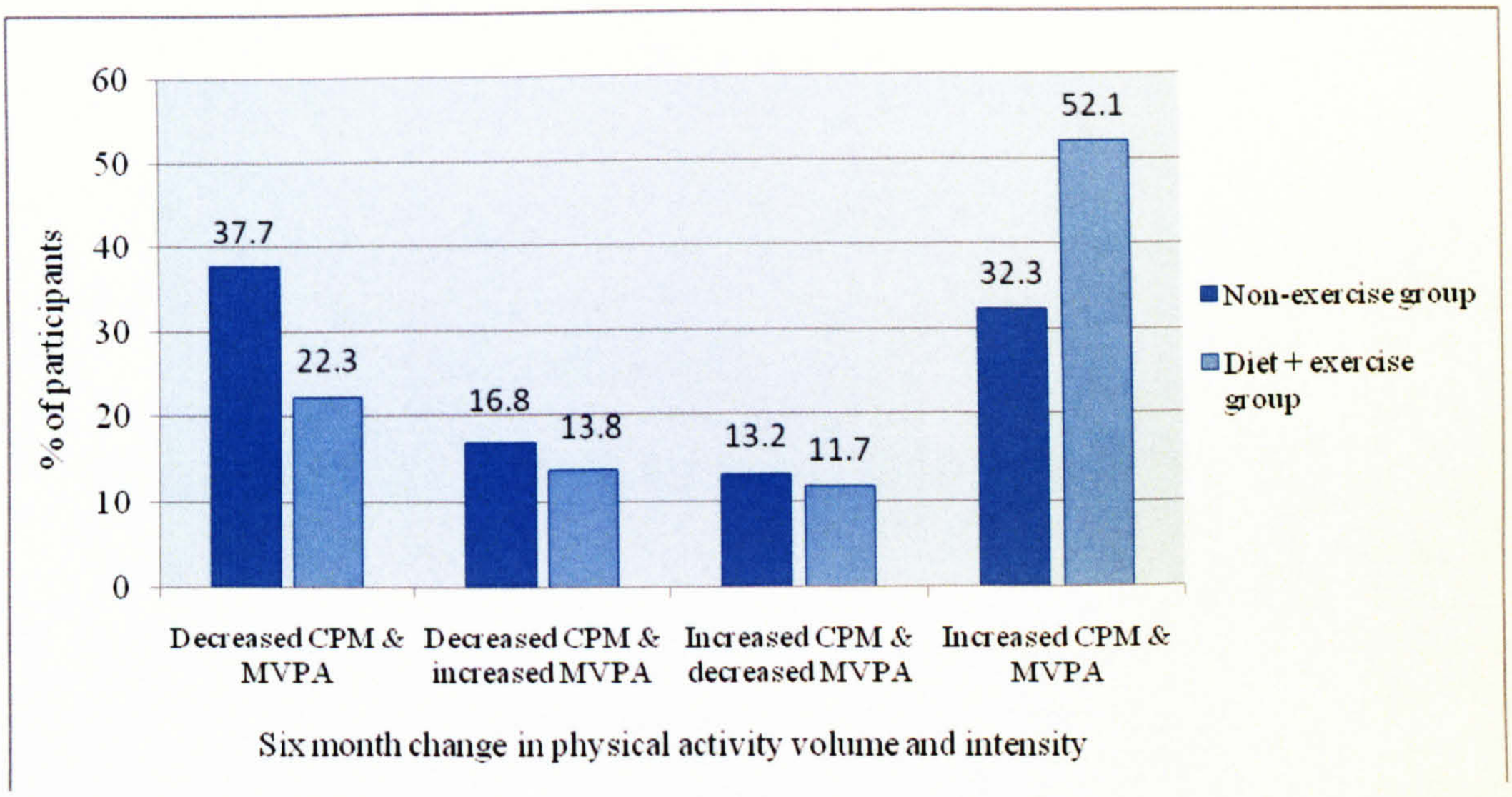
Figure 4.5. Percentage of participants accumulating 150 minutes of MVPA at baseline and six months by study group



All participants were categorised according to whether they increased or decreased the volume of physical activity and daily time spent in MVPA over the first six months of the Early ACTID Study. Four categories were created and the percentage of participants within each category is shown by group in Figure 4.6.

Over half of the *diet plus exercise* group increased both their volume of activity, as assessed by mean CPM, and the amount of time spent in MVPA. However, almost one quarter of participants performed less overall activity and spent less time in MVPA at six months compared to baseline. The majority (over one third) of *non-exercise* group participants registered a lower volume of activity and less MVPA at six months than at baseline. These data indicate that an increase in one aspect of physical activity, e.g. volume, does not necessarily guarantee an increase in another.

Figure 4.6. Six-month change in physical activity volume and time spent in MVPA by study group

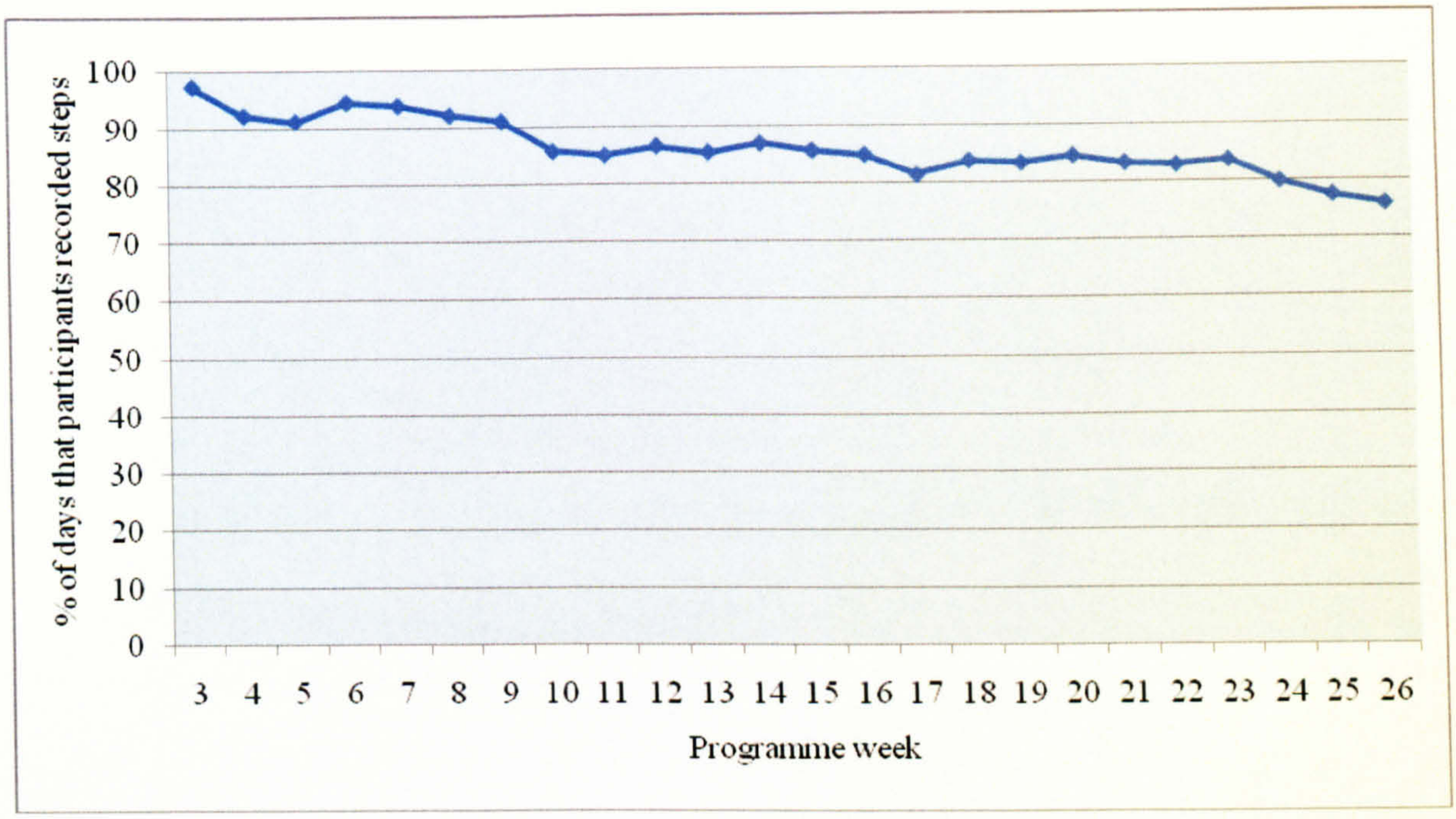


4.3.5. Self-monitoring and reporting of physical activity

Self-reported physical activity data were obtained from 121 participants in the *diet plus exercise* intervention group. One-hundred and fifteen participants (95%) from this group remained in the study at six months. Out of a possible 19,796 days between Week 3 and Week 26, physical activity diaries were kept on 17,086 days. This represents 86.3% compliance with keeping physical activity records. Compliance did not differ significantly between men (86.5%) and women (83.0%). Figure 4.7 shows the weekly compliance level up to six months. A dependent t-test showed that compliance with record keeping was significantly lower at Week 26 compared with Week 3 (mean difference -1.48 ± 2.81 days, $t(114)=-5.65$, $P<0.001$).

Reasons for not providing activity records over a prolonged period (>2 weeks) were reported by six participants. Reasons included injuries (n=2), bilateral foot surgery (n=1), depression (n=1), family bereavement (n=1), losing the completed records (n=1), and forgetting to use the diaries (n=1). Two participants refused to complete the records, but agreed to wear the pedometer for the duration of the intervention period.

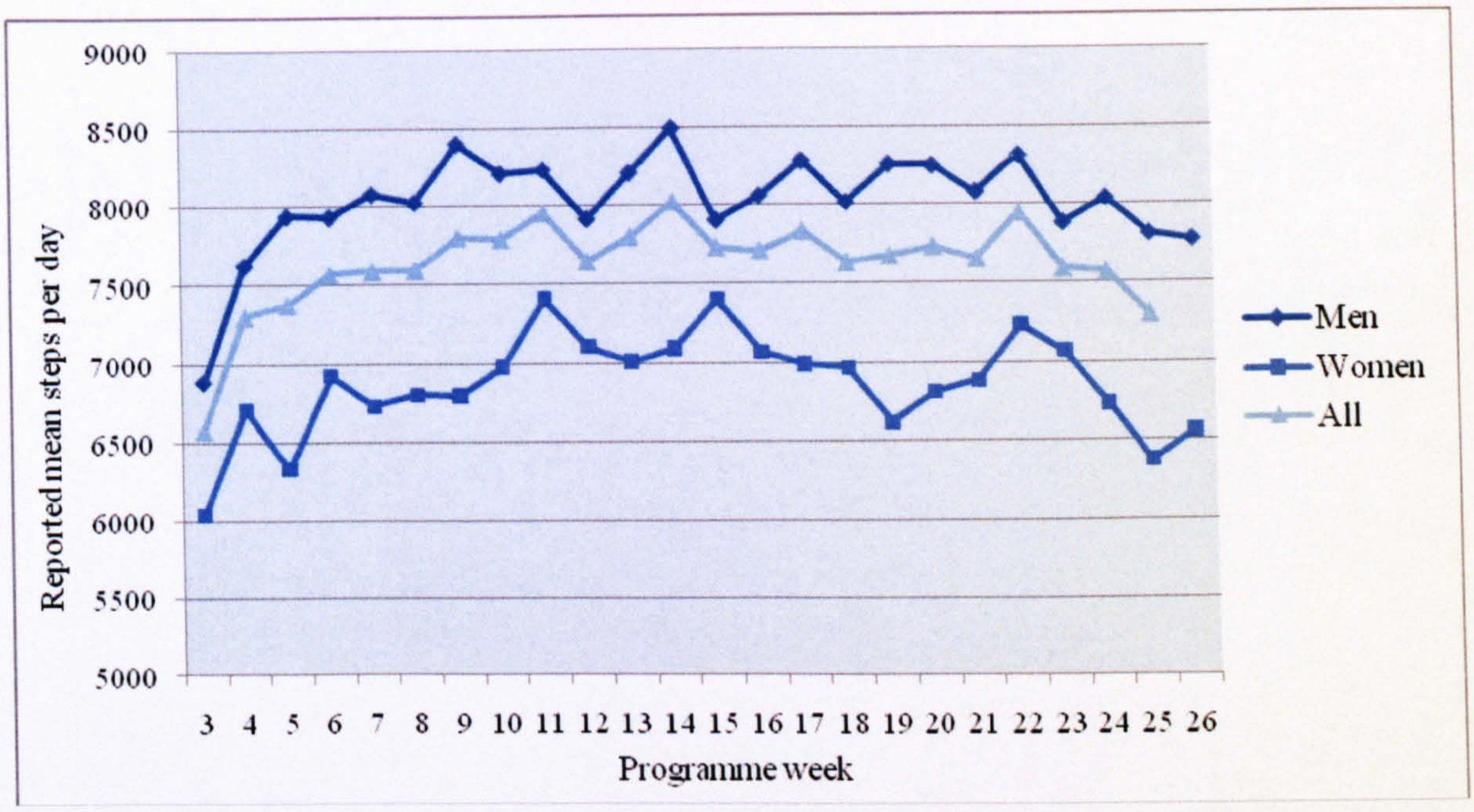
Figure 4.7. Compliance with physical activity diary recording from week 3 to week 26, as determined by the total number of days with steps reported



The weekly variation in reported mean daily steps up to six months is shown in Figure 4.8. Reported mean daily steps were significantly higher between Week 22 and 26 (7405.1 ± 2716.0) compared with Week 3 (6444.6 ± 2502.3) ($t(102)=3.80$, $P<0.001$). Daily steps peaked at Week 14 (8018.8 ± 3226.7). Just 7.4% of participants recording their steps at Week 3 accumulated a mean of at least 10,000 steps per day. This proportion increased significantly to 17.5% at six months (weeks 23 to 26) ($\chi^2(1)=15.16$, $P=0.02$).

Participants were asked to walk ≥3000 steps per day above values recorded in week 3 on at least five days per week. This equates to 71.4% of total days. Participants reported achieving the goal on 25.5 ± 21.7% (min 0%, max 91.2%) of the days where activity was recorded. Only seven (6%) participants reported meeting the goal on the target number of days.

Figure 4.8. Weekly variation in mean steps per day reported by participants randomised to the diet plus exercise group



There was a strong correlation between accelerometer counts and reported pedometer steps at both baseline ($r=.57$, $P<0.001$) and six months ($r=.67$, $P<0.001$). Figure 4.9 shows the association at baseline. Similar associations were found between pedometer steps and minutes of MVPA, as determined by accelerometry.

Figure 4.9. Scatter plot and correlation line of baseline mean steps per day versus mean accelerometer counts per minute in participants randomised to the diet plus exercise group

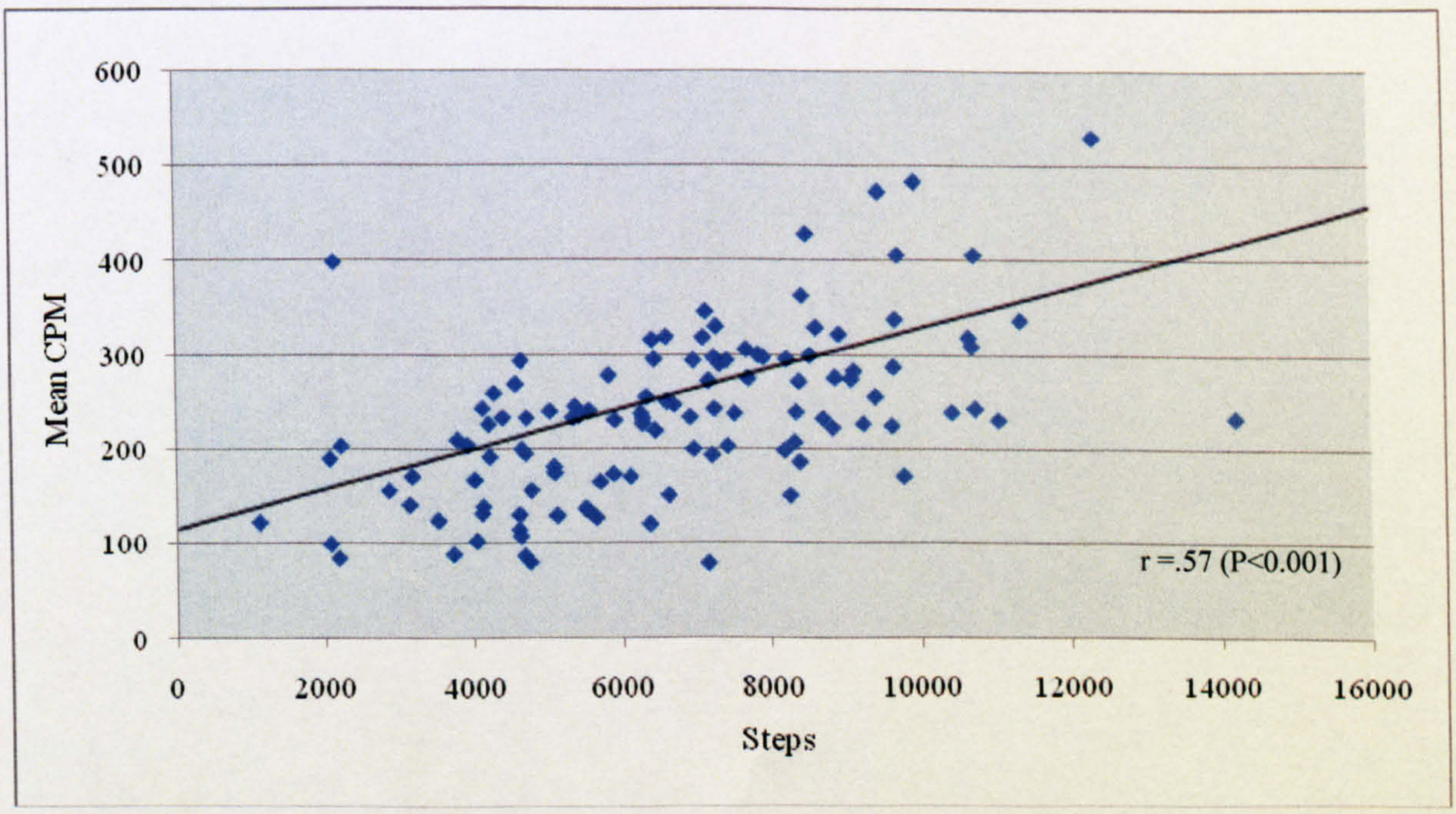


Table 4.5 shows the reported mean daily steps for participants who accumulated less than and greater or equal to 30 minutes of MVPA per day at baseline and at six months, as measured by the ActiGraph accelerometer. There was a significant difference in reported steps between groups at both time points (mean difference at baseline 2184.6, SE 510.3, $t(113)=4.28$, $P<0.001$, mean difference at six months 2508.4, SE 49.6, $t(89)=5.1$, $P<0.001$).

Table 4.5. Self-reported mean steps per day at week 3 and week 26 in relation to accumulating 30 minutes of MVPA per day, as measured by the ActiGraph among participants randomised to the diet plus exercise group

	Baseline				Six-months			
	N	Mean ± SD	Min	Max	N	Mean ± SD	Min	Max
Accumulating <30 minutes of MVPA per day	89	6152.4 ± 2408.0	1130.0	14188.0	55	6162.9 ± 2302.6	1733.0	11052.4
Accumulating ≥30 minutes of MVPA per day	26	8337.0 ± 1809.8	5570.0	12318.0	36	8671.3 ± 2337.7	3407.1	13318.7

4.4. Cardiorespiratory fitness

4.4.1. Compliance with the measurement protocol

Baseline measurement

Baseline cardiorespiratory fitness data are presented in Table 4.6a. With the exception of two participants who completed a cycle test due to peripheral neuropathy that contraindicated the walking test, all participants started the 1-MTW. Fitness data resulting from the two cycle tests have been excluded from analyses due to their incomparable nature. Twenty participants (5.9%) starting the walk test were unable to complete the 1-mile distance. Musculo-skeletal discomfort was reported by 14 participants as the reason for early termination, cardiorespiratory difficulty reported by two participants, 'other' reasons reported by three participants and for one participant there was a technical malfunction with the timing equipment. Mile end heart rate (HR) was lost for one participant due to a technical malfunction with the HR monitor.

One-mile time was recorded for all participants starting the walk test. For those 20 participants who were unable to walk the 1-mile distance the total time taken to complete the distance covered was used to

Table 4.6a. Baseline CRF test data collected from participants in the Early ACTID Study

	ALL		MEN		WOMEN		GENDER DIFFERENCE		
FITNESS OUTCOMES	N	Mean ± SD	N	Mean ± SD	N	Mean ± SD	P value	95% Confidence interval	
Mile end RPE	318	14.03 ± 1.52	197	14.01 ± 1.45	122	14.05 ± 1.63	0.80	-0.30	0.39
Mile end HR (beats per minute)	337	126.42 ± 20.57	206	123.63 ± 21.28	132	130.75 ± 18.68	**<0.01**	2.63	11.52
Mile end $\%HR_{max}$	337	78.66 ± 12.12	206	77.26 ± 12.82	132	80.84 ± 10.62	**<0.01**	0.93	6.19
Mile time (minutes)	338	16.95 ± 2.67	207	16.29 ± 2.56	132	17.96 ± 2.52	**<0.01**	1.13	2.24
Mile time (minutes)[a]	318	16.67 ± 2.34	195	16.04 ± 2.19	123	17.67 ± 2.23	**<0.01**	1.14	2.14
Mile time (minutes)[b]	295	16.18 ± 1.69	190	15.76 ± 1.73	105	16.95 ± 1.31	**<0.01**	0.84	1.55
$VO_{2max.pred}$ ($ml/kg/min^{-1}$)[c]	237	26.32 ± 8.21	144	30.03 ± 7.55	93	20.59 ± 6.35	**<0.01**	-11.22	-7.66

Data are means ± SD; HR, heart rate; $\%HR_{max}$, percentage of age-predicted maximum heart rate; $VO_{2max.pred}$, predicted maximal oxygen uptake; [a] completing 1-mile distance only; [b] completing the 1-mile distance within the parameters of the CRF inclusion criteria (<20 minutes); [c] only participants meeting the CRF inclusion criteria (Completing the 1-mile distance within 20 minutes, not prescribed beta blockers, and final heart rate not beyond 100% of age-predicted maximum).

Table 4.6b. Six-month CRF test data collected from participants in the Early ACTID Study

	ALL		MEN		WOMEN		GENDER DIFFERENCE		
FITNESS OUTCOMES	N	Mean ± SD	N	Mean ± SD	N	Mean ± SD	P value	95% Confidence interval	
Mile end RPE	294	13.71 ± 1.27	180	13.61 ± 1.27	114	13.89 ± 1.25	0.07	-0.17	0.58
Mile end HR (beats per minute)	295	126.47 ± 20.72	180	123.77 ± 21.75	115	130.69 ± 18.31	**<0.01**	2.10	11.73
Mile end $\%HR_{max}$	295	79.13 ± 12.20	180	77.75 ± 12.93	155	81.29 ± 10.64	**0.02**	0.70	6.38
Mile time (minutes)	296	16.47 ± 2.76	181	15.87 ± 2.87	155	17.40 ± 2.28	**<0.01**	0.91	2.15
Mile time (minutes)[a]	286	16.31 ± 2.45	176	15.74 ± 2.48	110	17.22 ± 2.12	**<0.01**	0.93	2.05
Mile time (minutes)[b]	269	15.85 ± 1.80	169	15.30 ± 1.66	100	16.77 ± 1.64	**<0.01**	1.06	1.88
$VO_{2max.pred}$ ($ml/kg/min^{-1}$)[c]	218	26.93 ± 8.58	128	31.25 ± 6.35	90	20.78 ± 7.55	**<0.01**	-12.39	-8.55

Data are means ± SD; HR, heart rate; $\%HR_{max}$, percentage of age-predicted maximum heart rate; $VO_{2max.pred}$, predicted maximal oxygen uptake; [a] completing 1-mile distance only; [b] completing the 1-mile distance within the parameters of the CRF inclusion criteria (<20 minutes); [c] only participants meeting the CRF inclusion criteria (Completing the 1-mile distance within 20 minutes, not prescribed beta blockers, and final heart rate not beyond 100% of age-predicted maximum).

estimate the 1-mile time. Table 4.6 shows the mean 1-mile time for all participants starting the walk test, the mean 1-mile time for participants completing the 1-mile distance only (considered valid mile time) (94%), and finally the mean time for only those completing the 1-mile distance within 20 minutes (87%), which is the cut point for appropriate use of the equation to predict VO_{2max}. Compared with participants completing the 1-mile distance within 20 minutes, those taking longer than 20 minutes had significantly higher BMIs (U=4644, P=0.005), were less active (U=2020, P<0.001) and spent less time in MVPA (U=1999, P<0.001).

Valid $VO_{2max.pred}$ data are presented for the 237 (70%) participants who completed the 1-mile distance within 20 minutes, were not prescribed beta-blocker medication at the time of testing, and had a final heart rate that was not greater than 100% of their age predicted maximum. Participants whose fitness data did not meet the inclusion criteria were significantly older (U=6936, P<0.001), heavier (U=10379.5 P=0.01), had higher BMIs (U=9620.5, P=0.004), were less active (U=6109, P<0.001), and spent less time in MVPA (U=6926, P=0.001) compared with those who met the inclusion criteria.

Six-month measurement

Six-month cardiorespiratory fitness data are presented in Table 4.6b. A total of 298 participants started a fitness test at six months. Of these, two performed a cycle test due to peripheral neuropathy and fitness data for these participants are not presented. Two-hundred and eighty-six participants completed the 1-mile walk test. Out of the ten participants unable to complete the 1-mile distance, seven reported musculoskeletal discomfort as the reason for early termination. A reason for early termination was not recorded for three non-completers. Twenty-one (6.6%) of the 319 participants remaining in the study at six months did not undergo fitness testing because of either illness or injury, or because of non-attendance at the appointment.

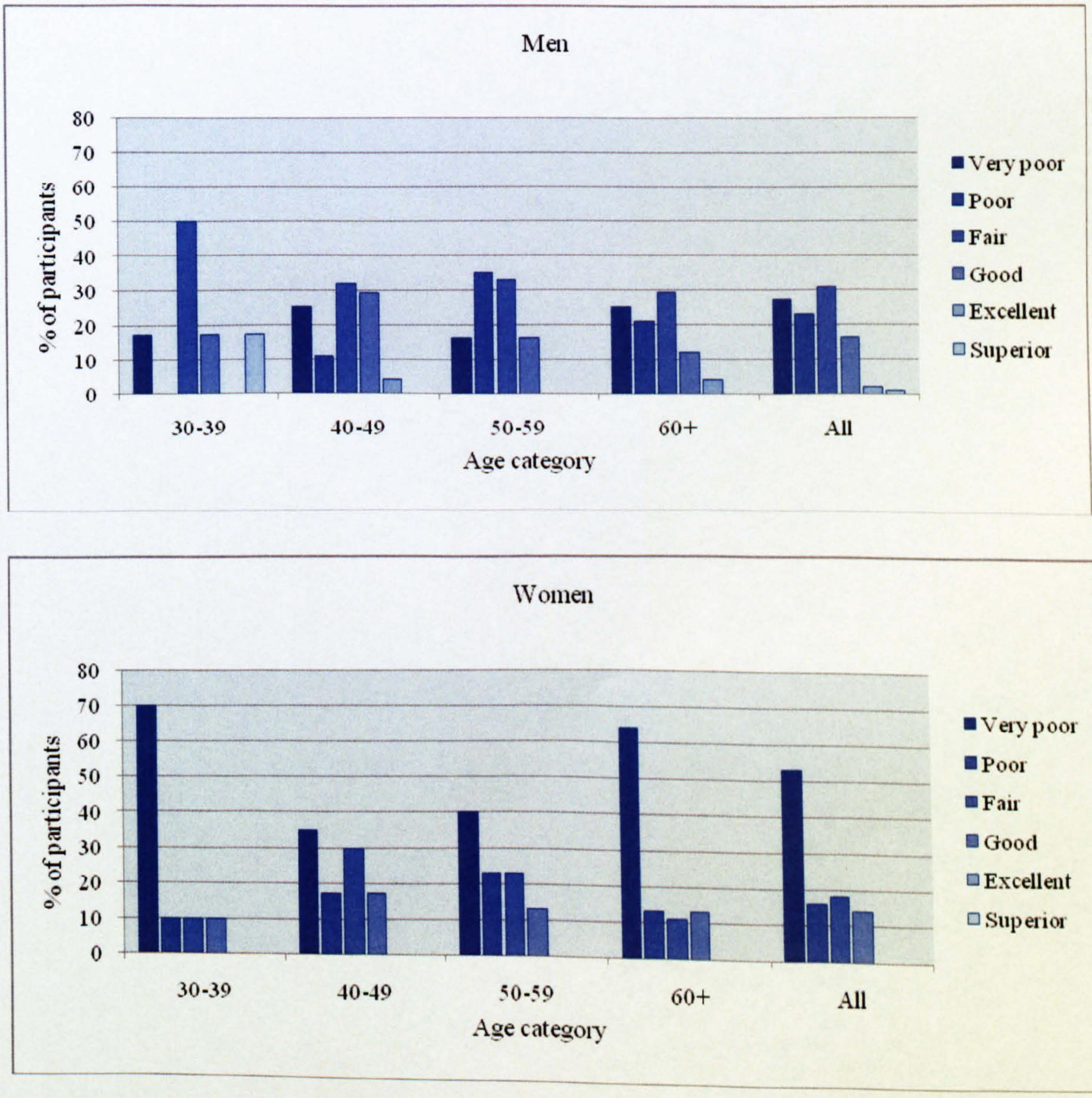
One-mile time was recorded for all participants starting the walk test. For those participants who were unable to walk the 1-mile distance (n=10, 3.4%), the total time taken to complete the distance covered was used to estimate the 1-mile time.

4.4.2. Levels of cardiorespiratory fitness

Baseline cardiorespiratory fitness

Figure 4.10 shows the percentage of participants within each age and gender-specific CRF category (Heyward, 2006). Data from participants prescribed beta blockers (n=53, 16%) have been excluded from this figure because of the attenuating effect on heart rate, which is used to predict VO_{2max}, and thus fitness category. Overall, 38% (n=108) of the study group were categorised as having 'very poor' fitness, 20% (n=57) as 'poor', 25% (n=73) as 'fair' and 15% (n=43) as 'good' fitness. Just 1.7% (n=5) of participants had an 'excellent' level of fitness and 0.3% (n=1) had a 'superior' fitness level.

Figure 4.10. Percentage of participants within each age and gender-specific CRF category at baseline, as published by Heyward



Six-month cardiorespiratory fitness

Overall, out of the 250 participants not prescribed beta blocker medication at the six-month fitness test, 32% (n=79) were categorised as having 'very poor' fitness, 14% (n=34) as 'poor', 30% (n=74) as 'fair', 20% (n=50) as 'good', and 4% (n=11) as 'excellent' fitness. Just 0.8% (n=2) had a 'superior' fitness level. The fitness profiles of participants at six months were slightly more favourable, with 25% in the top three fitness categories, compared with baseline profiles where just 17% of participants were categorised in the top three groups.

Change in cardiorespiratory fitness by study group

Mile time data were considered valid if they represented the actual time taken to complete a full mile, as opposed to a predicted mile time based on a part-completed mile. A valid mile time at both baseline and six months was obtained from 276 participants (93% of participants who performed the walk test at six months). As one group, participants took less time to complete the 1-mile distance at six months compared to baseline (mean difference -0.45 (1.07) minutes, $t(275)=7.02$), $P<0.001$). There was a strong association between the two times ($r=.89$, $P<0.001$).

There were 205 participants with valid $VO_{2max.pred}$ data at both time points. This represents 69% of those performing the 1-mile walk test at six months. A small but statistically significant increase in $VO_{2max.pred}$ was observed between baseline and six months post randomisation (mean difference 1.53 (3.24) ml/kg/min^{-1}, $t(204)=5.75$ $P<0.001$), and a strong association existed between the two measures ($r=.921$, $P<0.001$).

Independent t-tests revealed no significant differences between participants randomised to the *diet plus exercise* group and *non-exercise* groups in terms of 1-mile completion time or $VO_{2max.pred}$.

4.4.3. Cardiorespiratory fitness by demographic characteristics

Significant independent demographic predictors of 1-mile completion time were gender ($\beta=-1.637$, $t(316)=-6.455$, adjusted $R^2=.114$, $P<0.001$), age ($\beta=.092$, $t(316)=7.951$, adjusted $R^2=.164$, $P<0.001$), BMI ($\beta=.127$, $t(316)=5.013$, adjusted $R^2=.071$, $P<0.001$), CPM ($\beta=-.010$, $t(299)=-7.898$, adjusted $R^2=.170$, $P<0.001$), and MVPA ($\beta=-.482$, $t(299)=-7.501$, adjusted $R^2=.158$, $P<0.001$). As a model physical activity volume (CPM), age, gender and BMI explained 41% of the variance in 1-mile completion time during the submaximal fitness test.

Since the VO_{2max} prediction equation incorporates gender, age and weight, these variables, as well as BMI, were not entered into simple linear regression models. Accelerometer counts predicted $VO_{2max.pred}$ (β=.034, t(224)=6.323, adjusted R^2=.148, P<0.001), while MVPA as a predictor was slightly weaker but still highly significant (β=1.405, t(224)=5.111, adjusted R^2=.10, P<0.001).

Gender

Women walked at a slower pace during the 1-MTW (t(316)=6.46, P<0.001), worked at a higher percentage of the age predicted maximal heart rate (t(235)=2.67, P=0.008) and had a lower $VO_{2max.pred}$ (t(235)=-10.44, P<0.001) than men. Similar gender differences were found at six months. There was no significant difference between men and women in the rating of perceived exertion at the end of the 1-mile walk, and no gender differences were found in the six-month change in variables.

Age

Age was found to be strongly associated with time taken to complete the 1-mile distance (men, r=.501, P<0.001; women r=.403 P<0.001). As expected, since it is a component of the VO_{2max} prediction equation, age was inversely related with $VO_{2max.pred}$ (men, r=-.577, P<0.001; women, r=-.384, P<0.001). A weak inverse association between age and rating of perceived exertion was found in women at baseline only (r=-.196, P=0.03). The strength of these reported relationships was similar at six months. There was no association between age and mile-end percentage of age-predicted maximal heart rate.

BMI status

Differences between standard BMI groups, including normal/overweight (BMI <29.9), obesity (30.00-39.99) and morbid obesity (≥40), were examined by a one-way ANOVA, which showed a significant between-group difference in time to complete the 1-MTW (F(2,315)=9.35, P<0.001) and $VO_{2max.pred}$ (F(2,234)=27.07, P<0.001). Post-hoc Bonferroni analyses revealed that normal/overweight participants completed the 1-mile walk in a shorter time than both obese (P=0.009) and morbidly obese participants (P<0.001). Although morbidly obese participants walked more slowly than obese participants, differences were only borderline significant (P=0.08). Post-hoc analyses showed a significant difference in $VO_{2max.pred}$ between all BMI groups (P<0.001), with BMI being inversely related to $VO_{2max.pred}$. Differences between BMI groups did not differ between men and women. There were no significant differences between BMI groups in terms of the percentage of maximal heart rate at the end of the test and rating of perceived

exertion. This indicates that, despite the slower walking pace and lower predicted VO_{2max}, the relative intensity of the walk test was similar between BMI groups.

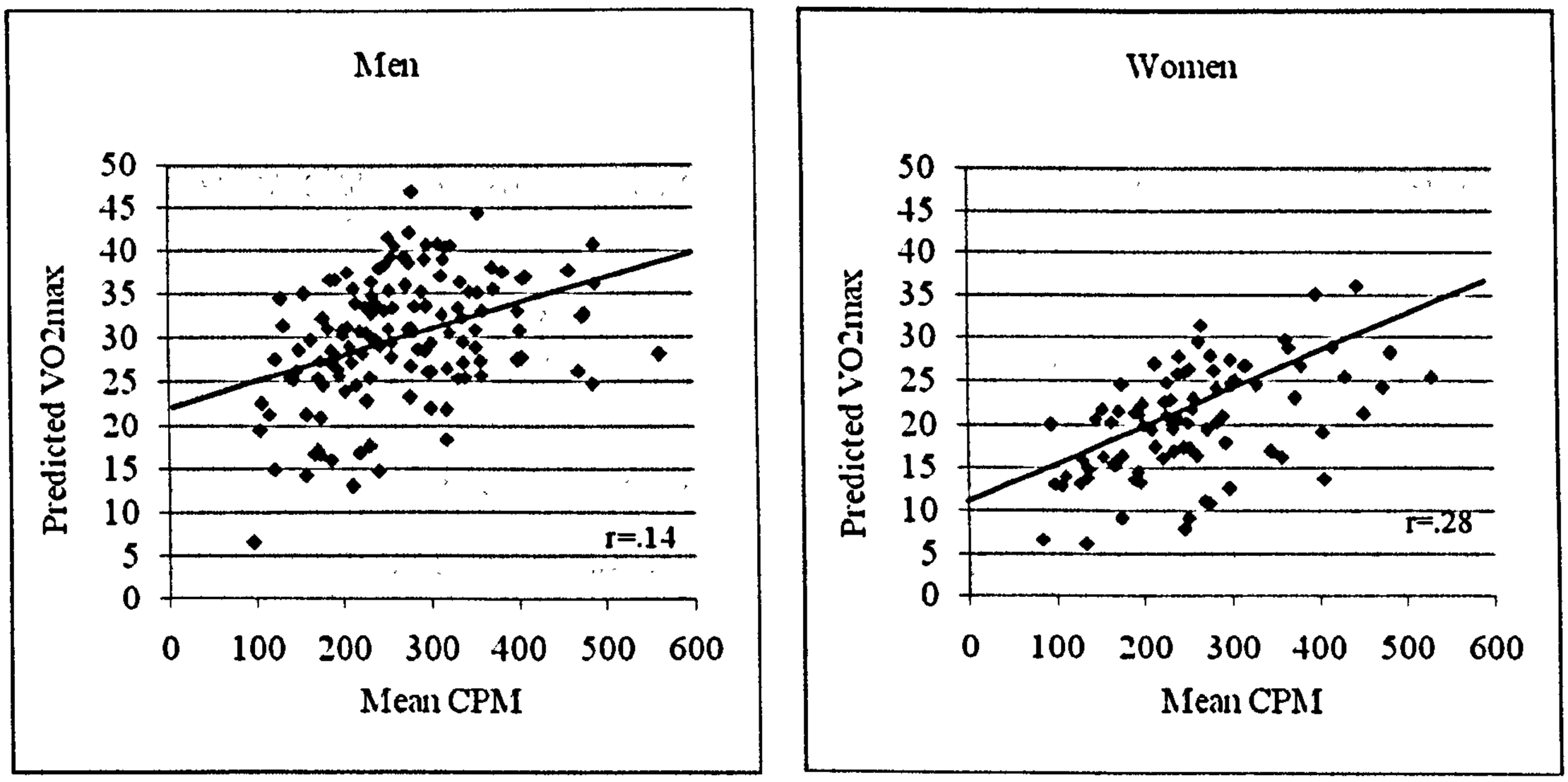
Physical activity level

Time to complete the 1-mile fitness test was inversely associated with physical activity volume (accelerometer CPM) ($r=-.415$, $P<0.001$) and time spent in MVPA ($r=-.349$, $P<0.001$). The strength of the associations were slightly weaker for predicted VO_{2max} (CPM, $r=-.348$, $P<0.001$; MVPA, $r=.298$, $P<0.001$), but still highly significant. Table 4.7 shows univariate linear regression analyses of physical activity volume (accelerometer CPM) and time spent in moderate to vigorous physical activity as predictors of 1-mile completion time and predicted VO_{2max} in men and women. Although physical activity explained a similar proportion of the variance in 1-mile completion time in both men and women, physical activity was a much stronger predictor of VO_{2max} in women than men. In both genders, physical activity volume appeared to be more important than time spent in MVPA. The associations between CPM and VO_{2max} are illustrated graphically in Figure 4.11.

Table 4.7. Univariate linear regression of physical activity volume (accelerometer CPM) and time spent in MVPA on 1-mile completion time and $VO_{2max.pred}$ at baseline and six months

	MEN				WOMEN			
	β coefficient	t	P value	Adjusted R^2	β coefficient	t	P value	Adjusted R^2
Mile Time								
CPM								
Baseline	-.414	-6.169	**<0.001**	.167	-.391	-4.518	**<0.001**	.145
Six month	-.337	-4.576	**<0.001**	.108	-.397	-4.176	**<0.001**	.149
Time spent in MVPA								
Baseline	-.363	-5.278	**<0.001**	.127	-.397	-4.591	**<0.001**	.150
Six month	-.376	-5.175	**<0.001**	.136	-.488	-5.359	**<0.001**	.230
VO_{2max}								
CPM								
Baseline	.376	4.737	**<0.001**	.135	.533	5.842	**<0.001**	.276
Six month	.345	4.009	**<0.001**	.112	.449	4.357	**<0.001**	.191
Time spent in MVPA								
Baseline	.236	2.827	**0.005**	.049	.491	5.229	**<0.001**	.232
Six month	.291	3.316	**0.001**	.077	.556	5.754	**<0.001**	.300

Figure 4.11. Scatterplot and correlation line of mean accelerometer counts per minute versus $VO_{2max.pred}$ in men and women at baseline



4.5. Associations between physical activity, cardiorespiratory fitness, glycaemic control and the metabolic syndrome

Glycaemic control (HbA_{1c}) was not associated with either physical activity volume (accelerometer CPM r=-.083) or time spent in MVPA (r=-.131) at baseline. Nor was it associated with either predicted VO_{2max} (r=.02) or 1-mile completion time (r=.12). Six month data also showed no relationship between these variables. Consequently, no further analyses were undertaken with glycaemic control as an outcome, and the primary research hypotheses stating that physical activity and cardiorespiratory fitness are associated with HbA_{1c} were rejected. The remaining section will explore associations between physical activity, fitness and the clustering of cardiovascular risk factors.

4.5.1. Physical activity and cardiovascular risk factors

A univariate logistic regression model was fitted to the data to test the research hypothesis that physical activity volume predicted the presence of the metabolic syndrome. The physical activity exposure variables, accelerometer CPM and the time spent in MVPA, were entered in their continuous form. Table 4.8 shows the unadjusted odds ratios of the metabolic syndrome, according to IDF criteria, for each physical activity exposure at baseline (n=318) and six months (n=272). The odds of the metabolic syndrome show that as CPM or MVPA increase, the odds of the metabolic syndrome decrease. The odds did not change after adjustment for age and gender.

Figure 4.11. Scatterplot and correlation line of mean accelerometer counts per minute versus $VO_{2max.pred}$ in men and women at baseline

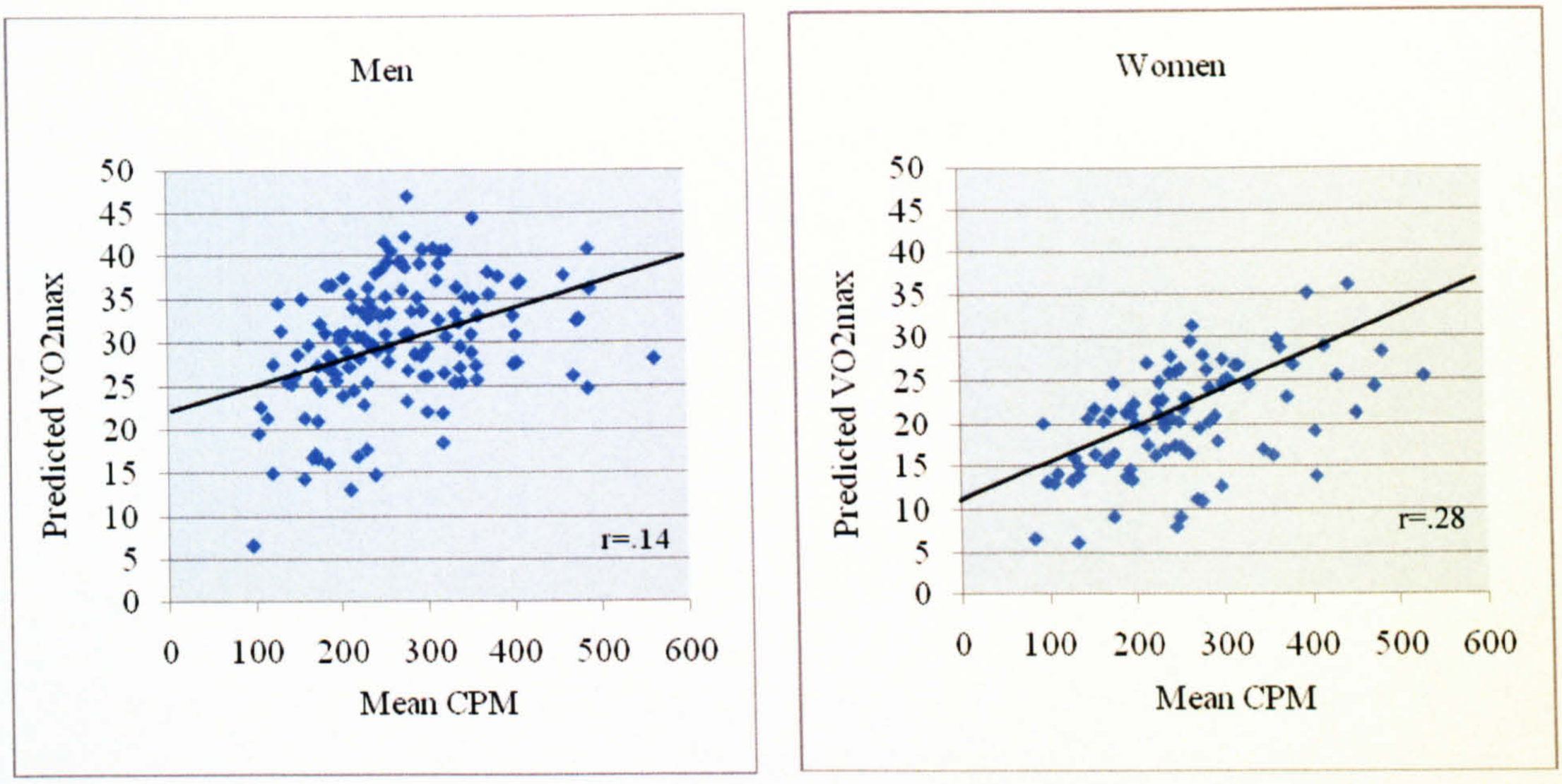


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Table 4.8. Unadjusted odds of the metabolic syndrome by accelerometer CPM and time spent in MVPA at baseline and six months

Predictor	β	SE β	Wald χ^2	P value	Exp(β) (95% Confidence interval)
CPM					
Baseline	-.003	.001	6.362	**0.012**	.997 (.995-.999)
Six month	-.004	.001	12.096	**0.001**	.996 (.993-.998)
Time spent in MVPA					
Baseline	-.166	.060	7.624	**0.006**	.847 (.753-.953)
Six month	-.326	.070	21.476	**<0.001**	.722 (.629-.829)

As can be seen in Figure 4.12, the proportion of participants with the metabolic syndrome generally decreased among increasing physical activity quartiles. This trend was evident for both physical activity volume and time spent in MPVA. Chi square analyses revealed that differences between quartile groups were significant in women only (CPM χ^2 (3)=11.56, P=0.009; MVPA χ^2 (3)=8.71, P=0.033).

Figure 4.12. Percentage of participants with the metabolic syndrome by gender and physical activity quartile at baseline

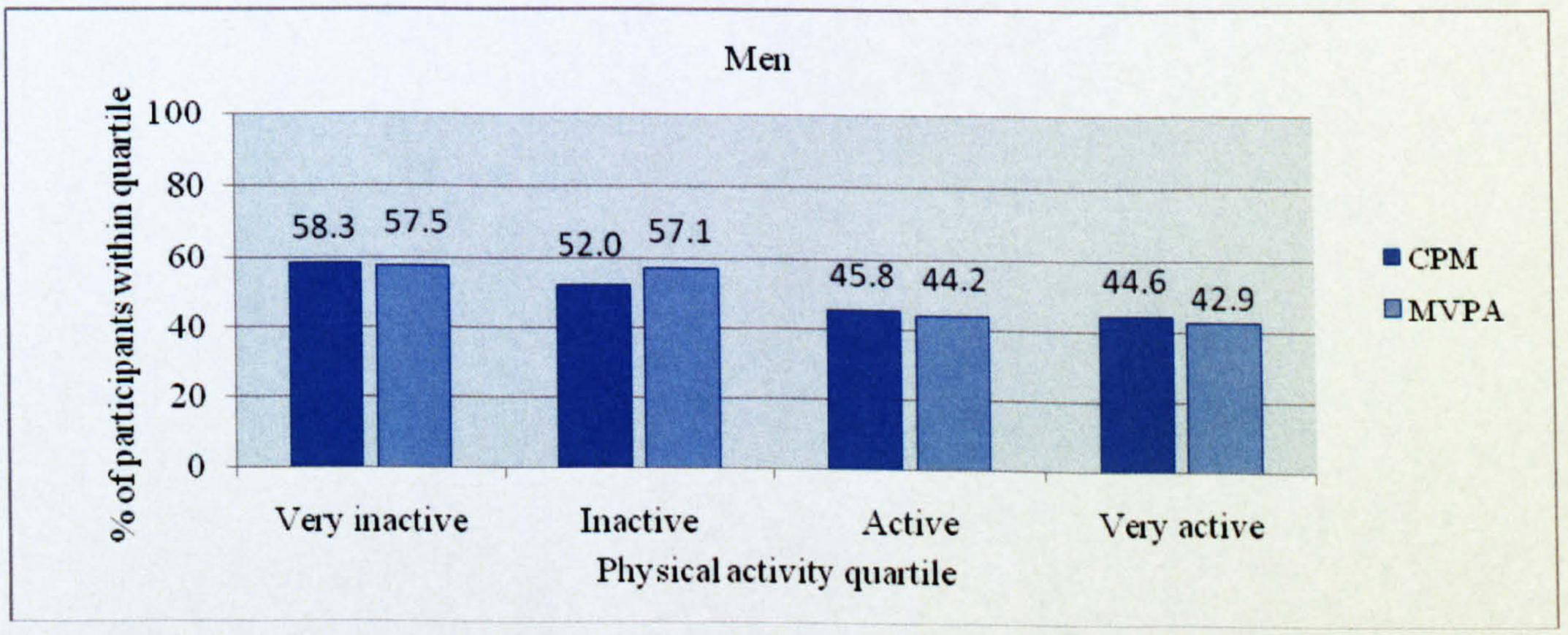


Table 4.9 shows the unadjusted odds ratios of the metabolic syndrome by quartile of physical activity volume and time spent in MVPA at baseline. Compared to the lowest physical activity quartile, which was entered as the reference group, increasing physical activity quartiles were associated with significantly lower odds of the metabolic syndrome in women. Men also appeared to have lower odds of the metabolic syndrome with increasing physical activity levels, however the 95% confidence intervals crossed 1.0, indicating that the associations were not significant.

Table 4.9. Unadjusted odds ratios of the metabolic syndrome by physical activity quartile at baseline and six months

	Odds ratio (95% Confidence interval)		
Predictor	All	Men	Women
CPM			
Baseline			
Quartile 1: Very inactive	1.0	1.0	1.0
Quartile 2: Inactive	**.499 (.257-.970)***	.774 (.326-1.836)	**.331 (.110-.989)***
Quartile 3: Active	**.339 (.175-.655)****	.774 (.326-1.836)	**.175 (.061-.501)****
Quartile 4: Very active	**.394 (.203-.764)****	.576 (.247-1.343)	.323 (.101-1.030)
Six months			
Quartile 1: Very inactive	1.0	1.0	1.0
Quartile 2: Inactive	.918 (.464-1.819)	.913 (.378-2.204)	.900 (.299-2.710)
Quartile 3: Active	**.423 (.213-840)***	.419 (.174-1.010)	.437 (.143-1.334)
Quartile 4: Very active	**.293 (.145-.595)****	**.368 (.156-.867)***	**.197 (0.53-.732)***
MVPA			
Baseline			
Quartile 1: Very inactive	1.0	1.0	1.0
Quartile 2: Inactive	.783 (.406-1.511)	.986 (.411-2.365)	.595 (.214-1.654)
Quartile 3: Active	**.395 (.206-.758)***	.586 (.255-1.347)	**.244 (.082-.724)****
Quartile 4: Very active	**.395 (.206-.758)***	.554 (.244-1.259)	**.282 (.091-.879)***
Six months			
Quartile 1: Very inactive	1.0	1.0	1.0
Quartile 2: Inactive	**.370 (.183-.751)****	**.346 (.135-.887)****	.485 (.160-1.471)
Quartile 3: Active	**.393 (.194-.796)****	.548 (.215-1.395)	**.247 (.081-.751)***
Quartile 4: Very active	**.139 (.065-.296)****	**.150 (.057-.396)****	**.150 (.057-.396)****

* P<0.05, ** P<0.01

Table 4.10 shows the unadjusted odds ratios of the metabolic syndrome by achievement of recommended levels of physical activity, including: 1) accumulating 150 minutes of at least moderate intensity activity per week, and 2) accumulating ≥30 minutes of at least moderate intensity activity on five or more days per

Table 4.10. Unadjusted odds ratios of the metabolic syndrome by achievement of recommended levels of physical activity at baseline and six months

		ALL			MEN			WOMEN		
		Metabolic syndrome n (%)			Metabolic syndrome n (%)			Metabolic syndrome n (%)		
		No	Yes	OR (95% CI)	No	Yes	OR (95% CI)	No	Yes	OR (95% CI)
Accumulating 150 min·wk^{-1}										
Baseline	No	61 (40.7%)	89 (59.3%)	1.0	42 (51.9%)	39 (48.1%)	1.0	19 (27.5%)	50 (72.5%)	1.0
	Yes	65 (59.1%)	45 (40.9%)	**.475 (.288-.783)****	46 (56.8%)	35 (43.2%)	.819 (.441-1.522)	19 (65.5%)	10 (34.5%)	**.200 (.079-.507)****
Six months	No	46 (46.9%)	52 (53.1%)	1.0	35 (57.4%)	26 (42.6%)	1.0	11 (29.7%)	26 (70.3%)	1.0
	Yes	64 (71.1%)	26 (28.9%)	**.359 (.196-.658)****	46 (70.8%)	19 (29.2%)	.556 (.266-1.162)	18 (72.0%)	7 (28.0%)	**.165 (.054-.505)****
Accumulating 30 min·day^{-1} ≥5 days·week^{-1}										
Baseline	No	99 (42.1%)	136 (57.9%)	1.0	70 (51.5%)	66 (48.5%)	1.0	30 (34.5%)	57 (65.5%)	1.0
	Yes	46 (55.4%)	37 (44.6%)	**.344 (.162-.730)****	18 (69.2%)	8 (30.8%)	.471 (.192-1.157)	8 (72.7%)	3 (27.3%)	**.197 (.049-.799)***
Six months	No	83 (43.9%)	106 (56.1%)	1.0	62 (61.4%)	39 (38.6%)	1.0	23 (43.4%)	30 (56.6%)	1.0
	Yes	59 (71.1%)	24 (28.9%)	.443 (.194-1.012)	19 (76.0%)	6 (24.0%)	.502 (.184-1.307)	6 (66.7%)	3 (33.3%)	.383 (.087-1.697)

OR, Crude odds ratio; CI, confidence interval; * P<0.05, ** P<0.01

week. Sufficient data to examine these associations were provided by 260 participants at baseline and 188 participants at six months. Odds ratios were estimated relative to not meeting the recommended levels of activity. As one cohort, accumulating ≥150 minutes of at least moderate intensity physical activity over seven days was associated with significantly lower odds of the metabolic syndrome at both baseline and six months, compared to those not accumulating ≥150 minutes. Accumulating ≥30 minutes of at least moderate intensity activity on five or more days per week was associated with even lower odds of the metabolic syndrome; however, these were not significant at six months.

When examined by gender, engaging in recommended activity levels appeared to be associated with significantly lower odds of the metabolic syndrome in women only. Although in men there was a trend for lower odds in those meeting the recommended level of physical activity, this was not significant.

4.5.2. Cardiorespiratory fitness and cardiovascular risk factors

Univariate logistic regression models were fitted to the data to test the research hypothesis that cardiorespiratory fitness predicted the presence of the metabolic syndrome. The exposure variables, 1-mile completion time and predicted VO_{2max}, were entered in their continuous form. Table 4.11 shows the unadjusted odds of the metabolic syndrome, according to IDF criteria, for each fitness exposure at baseline and six months. The analyses show that both mile time and $VO_{2max.pred}$ were significant predictors of the metabolic syndrome. Higher mile times and lower $VO_{2max.pred}$ values were associated with higher odds of the metabolic syndrome. Although age was identified in the previous chapter as a potential covariate, correlation matrices showed no association between this and mile time, and so it was not entered as a confounder into the regression model. Furthermore, the VO_{2max} model was not adjusted for age, BMI and gender since these are used in the VO_{2max} prediction equation.

Table 4.11. Unadjusted odds of the metabolic syndrome by 1-mile completion time and $VO_{2max.pred}$ by gender at baseline and six months

Predictor	β	SE β	Wald χ^2	P value	Exp(β) (95% Confidence interval)
MEN					
Mile time					
Baseline (n=193)	.198	.073	7.400	**0.007**	1.219 (1.057-1.406)
Six month (n=173)	.142	.062	5.205	**0.023**	1.153 (1.020-1.303)
$VO_{2max\ pred}$					
Baseline (n=143)	-.096	.028	12.280	**<0.001**	.908 (.860-.958)
Six month (n=126)	-.070	.031	5.199	**.023**	.933 (.878-.990)
WOMEN					
Mile time					
Baseline (n=121)	.227	.098	5.390	**0.020**	1.255 (1.036-1.520)
Six month (n=110)	.307	.104	8.795	**0.003**	1.360 (1.110-1.666)
$VO_{2max\ pred}$					
Baseline (n=92)	-.141	.041	11.778	**0.001**	.869 (.802-.941)
Six month (n=89)	-.105	.033	10.151	**0.001**	.900 (.844-.960)

The presence of the metabolic syndrome was examined by gender-specific CRF quartile group. The mean $VO_{2max.pred}$ values in men were 20.86 ± 4.73, 28.19 ± 1.28, 32.50 ± 1.47 and 38.57 ± 2.60 ml·kg·min^{-1} for the very unfit, unfit, fit and very fit groups, respectively. In women, the corresponding $VO_{2max.pred}$ values were 12.31 ± 2.99, 18.61 ± 1.57, 22.82 ± 1.48 and 28.50 ± 2.85 ml·kg·min^{-1}, respectively. As can be seen in Figure 4.13, the proportion of participants with the metabolic syndrome decreased with each increasing CRF group. Chi square analyses revealed that differences between groups were highly significant in both men (χ^2 (3)=13.94, P=0.002) and women (χ^2 (3)=14.55, P=0.002).

Figure 4.13. Percentage of participants with the metabolic syndrome by gender and $VO_{2max.pred}$ quartile at baseline

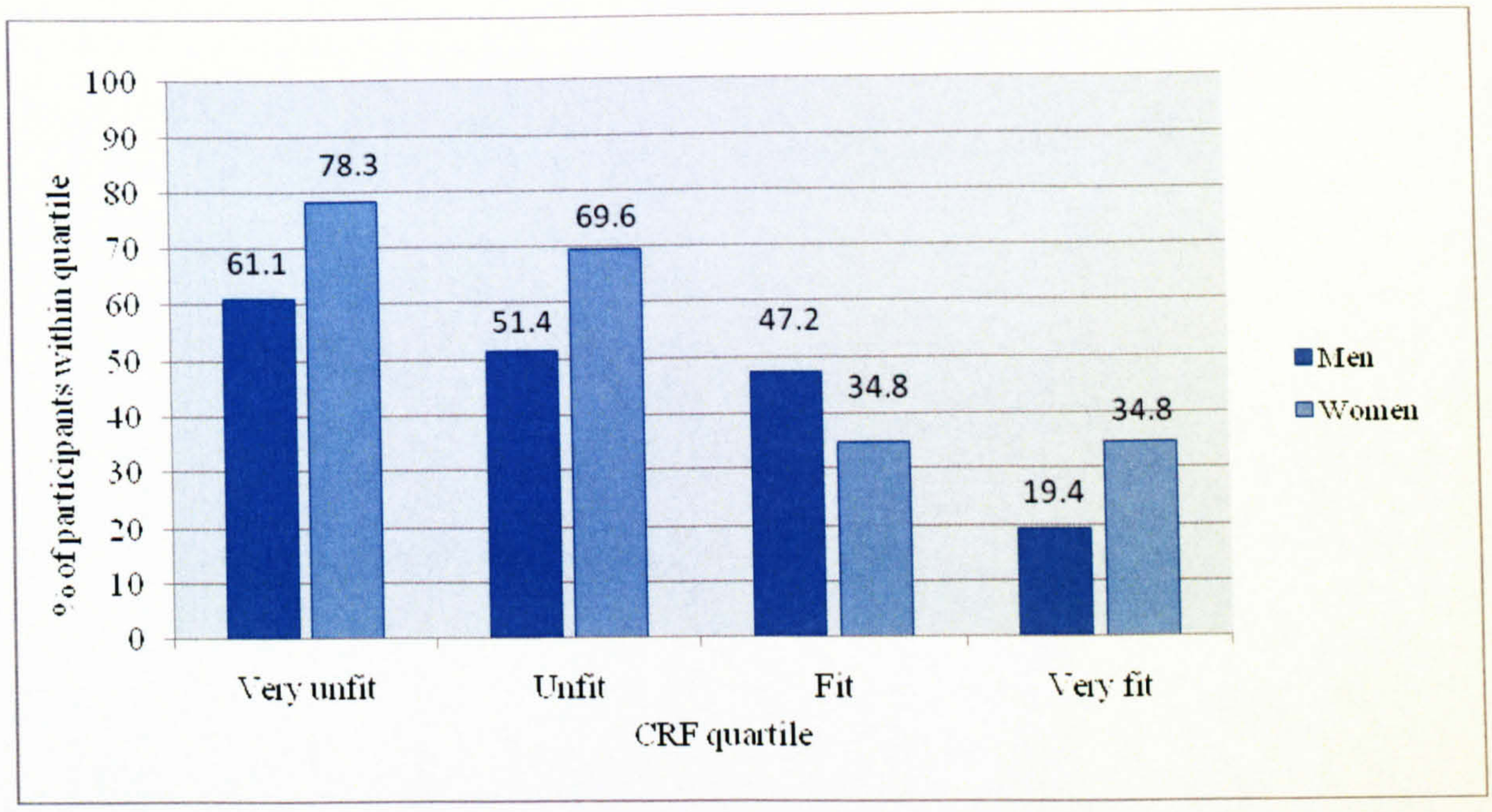


Table 4.12 shows the unadjusted odds ratios of the metabolic syndrome by gender-specific quartile of 1-mile completion time and predicted VO_{2max}. The group taking the most time to complete the 1-mile distance was entered as the reference group in the logistic regression model. Although there was a trend for the 1-mile completion time to predict the presence of the metabolic syndrome in the whole group, with the lowest odds associated with the fastest mile time, when analysed by gender this trend was not significant in women.

Compared to the lowest predicted VO_{2max} quartile, which was entered as the reference group, increasing CRF quartile groups were associated with significantly lower odds of the metabolic syndrome in women ($P<0.01$). Men also appeared to have lower odds of the metabolic syndrome with increasing CRF levels, however, only the highest fitness quartile was associated with odds that were significantly lower than the reference group. Predicted VO_{2max} appears to be a stronger predictor of the metabolic syndrome than 1-mile walk time.

Table 4.12. Unadjusted odds ratios of the metabolic syndrome by $VO_{2max.pred}$ quartile at baseline and six months

	Odds ratio (95% Confidence interval)		
Predictor	All	Men	Women
Mile time			
Baseline			
Quartile 1: Very slow time	1.0	1.0	1.0
Quartile 2: Slow time	.916 (.481-1.745)	.712 (.317-1.600)	1.437 (.154-1.243)
Quartile 3: Fast time	**.521 (.276-.986)***	.580 (.259-1.297)	.438 (.154-1.243)
Quartile 4: Very fast time	**.350 (1.83-.671)****	**.328 (.142-.754)****	.382 (.134-1.090)
Six months			
Quartile 1: Very slow time	1.0	1.0	1.0
Quartile 2: Slow time	**.481 (.245-.944)***	.551 (.235-1.290)	.357 (.109-1.166)
Quartile 3: Fast time	**.481 (.245-.944)***	.572 (.243-1.344)	.330 (.102-1.065)
Quartile 4: Very fast time	**.227 (.111-.464)****	**.258 (.101-.657)****	**.159 (.048-.523)****
$VO_{2max\ pred}$			
Baseline			
Quartile 1: Very low CRF	1.0	1.0	1.0
Quartile 2: Low CRF	.673 (.316-1.433)	.674 (.263-1.729)	.635 (.168-2.402)
Quartile 3: High CRF	**.349 (.165-.741)****	.569 (.223-1.453)	**.142 (.040-.549)****
Quartile 4: Very high CRF	**.162 (.073-.361)****	**.154 (.053-.445)****	**.148 (.040-.549)****
Six months			
Quartile 1: Very low CRF	1.0	1.0	1.0
Quartile 2: Low CRF	.549 (.255-1.179)	.401 (.145-1.112)	.804 (.219-2.943)
Quartile 3: High CRF	**.424 (.197-.915)***	.604 (.224-1.624)	**.241 (.069-.848)***
Quartile 4: Very high CRF	**.234 (.103-.533)****	**.269 (.090-.802)***	**.175 (.048-.641)****

* P<0.05, ** P<0.01

Table 4.13 shows the unadjusted odds ratios of the metabolic syndrome by level of fitness at baseline and six months. Fitness level was determined by stratifying valid $VO_{2max.pred}$ values above and below the gender-specific median. Sufficient data to examine these associations were provided by 92 women and 143 men at baseline and 89 women and 126 men at six months. The mean $VO_{2max.pred}$ values in men were 24.52 ± 5.05 and 35.54 ± 3.70 $ml\,kg\,min^{-1}$ for the low fit and high fit groups, respectively. In women, the corresponding $VO_{2max.pred}$ values were 15.46 ± 3.97 and 25.60 ± 3.63 $ml\,kg\,min^{-1}$, respectively. Odds ratios were estimated relative to being in the low fitness category. As one cohort, the high fit group had much lower odds of the metabolic syndrome than the low fit group. When analysed by gender, fitness category appeared to be a stronger predictor of the metabolic syndrome in women than men. Although this trend was also apparent at six months, the lower odds of the metabolic syndrome associated with the high fit group were only significant in women when the associations were examined by gender.

Table 4.13. Adjusted odds ratios of the metabolic syndrome by fitness above and below the gender-specific median of $VO_{2max.pred}$ at baseline and six months

			ALL			MEN			WOMEN		
			Metabolic syndrome n (%)			Metabolic syndrome n (%)			Metabolic syndrome n (%)		
			No	Yes	OR (95% CI)	No	Yes	OR (95% CI)	No	Yes	OR (95% CI)
Baseline											
	Below the median (Low fit)	No	43 (36.4%)	74 (63.2%)	1.0	31 (43.7%)	40 (56.3%)	1.0	12 (26.1%)	34 (73.9%)	1.0
	Above the median (High fit)	Yes	78 (66.1%)	40 (33.9%)	**.298 (.174-.509)****	48 (66.7%)	24 (33.3%)	**.388 (.197-.764)****	30 (65.2%)	16 (34.8%)	**.188 (.077-.461)****
Six-month											
	Below the median (Low fit)	No	50 (46.3%)	58 (53.7%)	1.0	37 (57.8%)	27 (42.2%)	1.0	13 (29.5%)	31 (70.5%)	1.0
	Above the median (High fit)	Yes	71 (66.4%)	36 (33.6%)	**.437 (.252-.759)****	42 (67.7%)	20 (32.3%)	.653 (.315-1.351)	29 (64.4%)	16 (35.6%)	**.231 (.095-.563)****

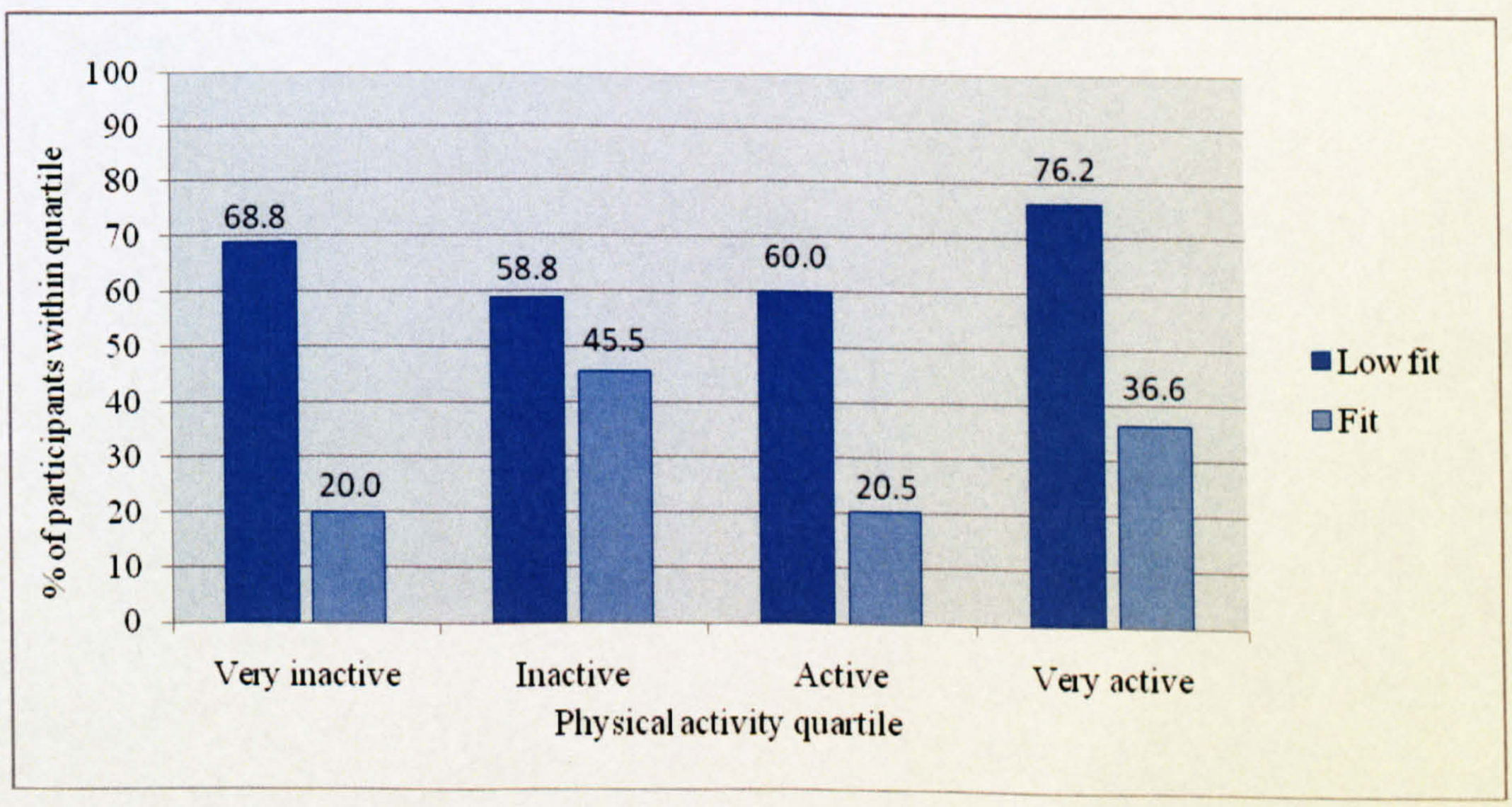
OR, Crude odds ratio; CI, confidence interval; * P<0.05, ** P<0.01

4.5.3. Relative importance and interaction effects of physical activity and cardiorespiratory fitness on cardiovascular risk factors

In order to determine the relative importance of physical activity and CRF with the metabolic syndrome, both exposure variables were entered into the linear regression model in their continuous form. The model was not adjusted for age, BMI and gender since these are used to predict VO_{2max}. When entered together, physical activity was no longer a significant predictor of the metabolic syndrome (β=1.0, 95% CI .998 to 1.005); however, the strength of the relationship with CRF remained (β=.902, 95% CI .866 to .940).

With the purpose of determining whether there was an interactive effect between physical activity and CRF on the metabolic syndrome, univariate logistic regression models were fitted to the data to test the research hypothesis that there was an interaction effect of predicted VO_{2max} and physical activity volume (CPM) on the presence of the metabolic syndrome. Both predictors were multiplied together in their continuous form and entered into the model as an interaction exposure. No significant interaction effect was found. Figure 4.14 illustrates this. No further interaction analyses were performed.

Figure 4.14. Percentage of participants with the metabolic syndrome by fitness status and physical activity level at baseline



Chapter 5. Discussion

This chapter will summarise the principal findings of the study and then discuss these in relation to previous literature. Subsequently, the strengths and limitations of the study will be considered, followed by a discussion of the potential implications of the study's findings.

5.1. Interpretation of findings

5.1.1. Principal findings

The aims of this study were to: 1) develop intervention materials to facilitate change in physical activity levels, 2) describe objectively measured habitual physical activity, 3) examine change in physical activity over six months, 4) explore the use of pedometers and diaries to monitor daily physical activity over six months, 5) describe CRF levels, and 6) explore the independent and interactive cross-sectional associations of physical activity and CRF with HbA_{1c} and the clustering of cardiovascular risk factors among adults with recently diagnosed T2D recruited to the Early ACTID Study.

Glycaemic control and the clustering of cardiovascular risk factors

Three-hundred and forty participants with a diagnosis of T2D within the previous 5-8 months were recruited to the present study. Of these, 24% had optimal HbA_{1c} values (<6%) and a further 29% had values between 6 and 6.49%, which represents good control. Despite relatively well controlled HbA_{1c}, 54% of participants were categorised as having the metabolic syndrome according to IDF criteria.

Objectively measured habitual physical activity

Accelerometry data were obtained from 321 participants at baseline. Physical activity volume was assessed by mean accelerometer counts per minute (CPM), while intensity was assessed by time spent in moderate to vigorous physical activity (MVPA) using a cut point of 2100 CPM. The study cohort registered a mean of 243 ± 97.17 CPM and 21.57 ± 17.62 minutes of MVPA per day at baseline. Among obese and morbidly obese participants only, daily physical activity levels were lower during the weekend compared with week days. Only 14% of participants (16% of men and 11% of women) accumulated ≥30 minutes of MVPA on at least five out of seven measurement days, which is the national recommendation for physical activity.

Almost 12% of participants (10% of men and 14% of women) were classed as sedentary, since they accumulated less than 30 minutes of MVPA per week.

Significant demographic predictors of participants' physical activity were age, BMI and gender. Women were 9% less active than men and spent 20% less time in MVPA. There was a significant interaction between age and BMI on level of physical activity. The strength of the inverse association between age and physical activity volume increased with increasing BMI. Although there was a strong inverse association between age and MVPA among participants within the morbidly obese BMI category, there was no such association in participants within the obese or normal/overweight BMI categories. BMI status was inversely related to physical activity volume and MVPA. Differences between BMI categories in CPM and time spent in MVPA were more pronounced at the weekend than during the week. Unsurprisingly, the proportion of participants meeting recommended levels of physical activity (≥30 minutes of MVPA on ≥5 days per week) decreased among increasing BMI groups.

Cardiorespiratory fitness

Just 70% of participants undergoing baseline fitness assessment provided data within the parameters of the VO_{2max} estimation regression equation. Mean $VO_{2max.pred}$ was 30.03 ± 7.55 ml kg min^{-1} for men and 20.59 ± 6.35 ml kg min^{-1} for women. When participants' predicted VO_{2max} values were classified according to six age and gender-specific CRF categories, which are based on normative data from a healthy population (Heyward, 2006), just 17% of participants had values that placed them in the top three fitness groups. Physical activity volume (CPM) appeared to be a stronger predictor of $VO_{2max.pred}$ than time spent in MVPA, and it explained a greater proportion of the variance in $VO_{2max.pred}$ in women than men (27.6% vs. 13.5%).

Associations between physical activity, cardiorespiratory fitness and metabolic and cardiovascular risk factors

Data from this study found no evidence of an association between HbA_{1c} and physical activity or cardiorespiratory fitness. In fact, HbA_{1c} was not found to be associated with age, gender, weight or BMI in this study population. As such, the first three study hypotheses, as described in Chapter 3, were rejected. In contrast, the presence of the metabolic syndrome, as defined according to IDF criteria, was inversely associated with physical activity and cardiorespiratory fitness. Compared to those not accumulating ≥30 minutes of MVPA on ≥5 days per week, the unadjusted odds ratio of the metabolic syndrome associated

with meeting the recommended level of activity was .344 (95% CI .196 to .658). Similarly, when participants were categorised below or above the gender-specific $VO_{2max\ pred}$ median, the odds ratio of the metabolic syndrome for those in the high fit group compared to the low fit group was .298 (95% CI .174 to .509). When examined by gender, low physical activity and low fitness were much stronger predictors of the metabolic syndrome in women than men. When both physical activity and $VO_{2max\ pred}$ were entered into the logistic regression model, physical activity was no longer significantly associated with the metabolic syndrome. No interaction effect was observed between physical activity and cardiorespiratory fitness on the presence of the metabolic syndrome.

Use of pedometers and daily physical activity records

Pedometer data were obtained from 121 participants in the *diet plus exercise* group. Compliance with keeping daily physical activity records was 86.3% over a six month period. Compliance at six months (76%) was lower compared with baseline (97%, P<0.001). Although pedometer and accelerometer data were not collected during the same week, since the pedometers were an intervention tool rather than an outcome measure, self-reported pedometer steps were moderately associated with objectively measured physical activity at both baseline (r=.57, P<0.001) and six months (r=.67, P<0.001). Compared with baseline, the number of self-reported daily steps was significantly higher at six months (6445 ± 2502 vs. 7405 ± 2716, t(102)=3.80, P<0.001) and a greater proportion of participants reported accumulating 10,000 steps per day (7.4% vs. 17.5%).

Physical activity level among diet plus exercise participants

Between baseline and six months, mean CPM increased by 11.1% (P=0.02) and time spent in MVPA by 25.24% (P=0.001) within the *diet plus exercise group*. The discrepancy in the increase between CPM and MVPA could indicate that some compensatory changes in levels of spontaneous physical activity took place, whereby some participants may have increased their overall sedentary time.

5.1.2. Comparisons with previous literature

Glycaemic control and the clustering of cardiovascular risk factors

In this study, the prevalence of the metabolic syndrome in men and women with recently diagnosed T2D was 60% and 50%, respectively, which is lower than the 80% prevalence estimated from large epidemiological studies (Hanefeld et al., 2007; Isomaa et al., 2001). There are a number of possible

explanations for this. The present study applied the relatively recent definition from the IDF, which will not have been used in studies undertaken prior to its publication in 2006. The use of different definitions between studies prevents direct comparisons from being drawn and will undoubtedly lead to differences in estimated prevalence rates. Nevertheless, recently published analyses of data from NHANES suggest that using the IDF definition of the metabolic syndrome results in a significantly higher prevalence compared with using the NCEP ATP III definition. This difference was consistent in both sexes and across all fitness levels.

The use of a BMI >30kg/m^2 to identify central obesity instead of waist circumference also could explain the identification of fewer people. Previous studies have found this can lead to substantially lower prevalence rates (Isomaa et al., 2001). Additionally, it is reasonable to expect a lower prevalence in people with a recent diagnosis of T2D compared to those who have had established diabetes for longer durations. Indeed, the prevalence figures in this study are similar to the 50% prevalence rate reported for people with impaired fasting glucose and/or impaired glucose tolerance (Isomaa et al., 2001). Finally, the fact that participants had volunteered to take part in a diet plus exercise intervention study means that this cohort is unlikely to be representative of the general diabetes population.

The higher prevalence of the metabolic syndrome in women than men is also inconsistent with prevalence figures reported previously for European adults (Hu et al., 2004b; Isomaa et al., 2001), and this may well be attributable to the self-selecting nature of the study population. Interestingly, among participants with T2D who had volunteered to participate in a long-term lifestyle intervention in the United States, the prevalence of the metabolic syndrome was also higher in women (94.8%) than men (92.9%) (Ribisl, Lang, Jaramillo et al., 2007).

Objectively measured habitual physical activity

The volume of physical activity registered by accelerometers in this study (243 ± 97 CPM) is much lower compared to the volume recently reported in a study population of healthy Swedish adults (376 ± 141 CPM) (Hagstromer, Oja and Sjostrom, 2007). Hagstromer and colleagues collected seven-day accelerometer data from 1114 healthy Swedish adults between 18 and 69 years (mean age 45 ± 15 years; mean BMI 25.0 ± 3.8). Daily MVPA was also lower in the Early ACTID cohort compared to the Swedish study population (17.8 (25th-75th percentile 8.2-30.9) vs. 29 (17-44) minutes), as was the proportion of people accumulating at least 30 minutes of MVPA daily (26% vs. 52%). While 36% of the Swedish

participants were overweight and 7% were obese, the majority had a healthy BMI, which could explain the difference in physical activity levels between the two groups, given the inverse association between BMI and physical activity found in both this study and several others (Cooper, Page, Fox et al., 2000; Plotnikoff et al., 2006).

In this present study, morbidly obese participants were consistently less active than their obese and normal/overweight counterparts. These differences were seen for the total volume of activity and time spent in MVPA, which is consistent with previous studies in both non-diabetic (Cooper et al., 2000) and diabetic participants (Tudor-Locke et al., 2002a). Furthermore, lower levels of daily physical activity at the weekend compared with during the week were evident in obese and morbidly obese participants only, and this too provides support to findings reported in a study of adults without diabetes (Cooper et al., 2000). This evidence suggests that obese individuals may choose to be less active than non-obese individuals in periods that are most likely to be free time.

Compared with published data from normal-weight, overweight and obese adults employed in sedentary occupations (Cooper et al., 2000), physical activity volume and time spent in MVPA was substantially lower in participants with T2D. There were considerable differences in the overweight group on both week days ((T2D) 258.6 vs. (non-T2D) 389.9 CPM and 24.9 vs. 40.3 minutes of MVPA) and weekend days (257.6 vs. 400.2 CPM and 23.6 vs. 40.1 minutes of MVPA). Among obese participants, differences between those with T2D and those without the condition existed on weekdays only (242.1 vs. 279.1 CPM and 21.7 vs. 32.3 minutes of MVPA). Although these comparisons indicate that, even when matched for BMI, individuals with T2D are much less active than those who are otherwise healthy, it should be noted that , compared to the Early ACTID cohort, the participants in the non-diabetic study were younger (mean age 38.6 ± 9.3), and were all in employment. Furthermore, the obese group in the Cooper *et al.* study included just 12 individuals, and thus the comparisons highlighted here should be interpreted with caution.

Age was found to explain 5% of the variance in mean CPM and MVPA, while BMI explained 4%. The strength of the inverse relationship found between accelerometer-determined activity and age (r=-.28) and BMI (r=-.20) in this study is consistent with reports from adults without diabetes (r=-.30) (Cooper et al., 2000; Harris, Owen, Victor et al., 2008; Hays and Clark, 1999; Plotnikoff et al., 2006; Tudor-Locke et al., 2001). Although gender predicted time spent in MVPA, it was not a significant predictor of physical activity volume, which supports the findings in non-diabetic groups (Hagstromer et al., 2007).

Recommended physical activity levels

Compared to self-reported data from the Health Survey for England (HSE) (Department of Health, 2007), the objectively measured physical activity levels were lower in the participants of this study. In the Health Survey for England, 35% of men and 24% of women reported achieving 30 minutes of activity on five or more days per week. In comparison, just 16% of men and 11% of women in the present study achieved this activity level. This finding is not surprising given that self-reported activity levels are often over estimated and that participants in the present study were from a clinical population with a condition associated with obesity and sedentary behaviour. However, an unexpected finding was that just 10% of men and 14% of women could be classified as sedentary due to accumulating less than 30 minutes of MVPA per week. This is much lower than the 33% of male respondents and 50% of female respondents in the HSE who reported doing less than 30 minutes per week.

Based on self-reported physical activity levels, 71.9% of 1,614 Canadian adults with T2D were not achieving the recommended 150 minutes of physical activity per week (Plotnikoff et al., 2006). A younger age, male gender, higher education, higher income and lower BMI were associated with achieving the recommended level of physical activity.

The study of accelerometer-determined physical activity patterns in normal-weight, overweight and obese individuals without diabetes using accelerometry reported that ≥150 minutes of MVPA were accumulated per week by 81.9% and 58.3% of non-obese and obese participants, respectively (Cooper et al., 2000). When the accelerometer data from this present study were examined using similar criteria (accumulating ≥150 minutes of MVPA per week), 53.0%, 36.8% and 13.6% of normal/overweight, obese and morbidly obese achieved recommended activity levels, respectively. These proportions are substantially lower than those reported in non-diabetic groups.

Pedometer data

This study found a moderately strong relationship between accelerometer counts and self-reported steps per day ($r=.57$ at baseline and $r=.67$ at six months, $P<0.01$), despite accelerometer and pedometer measurement periods taking place during different weeks. Even stronger associations ($r=.74$, $P<0.0001$; $r=.78$, $P=0.02$) have been reported previously (Sugden, Sniehotta, Donnan et al., 2008; Tudor-Locke et al., 2002a), although this is likely to be attributable to the accelerometer and pedometer measures taking place concurrently. In the study reported by Tudor-Locke and colleagues (2002a), which involved evaluating

agreement between ActiGraph accelerometer outputs and Yamax pedometer outputs assessed under free-living conditions in 52 participants, accumulating an average of 32.7 ± 14.4 minutes of moderate intensity activity per day equated to a mean of 8064 ± 766 steps per day. This is consistent with the findings from the present study, which found that participants accumulating an average of ≥30 minutes of MVPA per day reporting a mean of 8337 ± 1809 steps at baseline and 8671 ± 2338 steps per day at six months.

The mean steps per day reported by participants in the *diet plus exercise group* at baseline (6445 ± 2502) were higher than the 4,194 steps per day reported by Bjørgaas and colleagues (2005), but were remarkably similar to the pedometer values previously reported from a similar group of adults with T2D (6662 ± 3080) (Tudor-Locke et al., 2002a). These values are slightly lower in comparison to samples without reported diabetes (Tudor-Locke and Myers, 2001b), including a bi-ethnic sample of 109 adults with a mean age of 44.9 ± 15.8 years (7370 ± 3080) (Tudor-Locke et al., 2001) and a study sub sample of 58 healthy adults, aged 22-82 (7781 ± 2807) (McClung, Zahiri, Higa et al., 2000). The values for free-living individuals in this present study are, however, higher than those reported for hospital-based individuals with T2D prior to a pedometer-based intervention study (Yamanouchi, Shinozaki, Chikada et al., 1995). Interestingly, the intervention group in the hospital-based study reported accumulating an average of 19,200 steps daily over six to eight weeks, which is much higher than the increase found within the *diet plus exercise* participants in this present study. Nevertheless, the shorter intervention duration and the use of hospital in-patients in the study reported by Yamanouchi and colleagues means that comparisons should be interpreted cautiously.

Compliance with keeping physical activity diaries was 86.3% over the initial six months of the physical activity intervention, which is 3% higher than the adherence to record keeping noted in the meta-analysis (Bravata et al., 2007). Additionally, the studies reporting diary use as part of the physical activity intervention included in the meta-analysis were shorter than the Early ACTID intervention, and thus these findings are particularly encouraging in terms of application, since the meta-analysis found that diary use was associated with increased physical activity.

Change in physical activity

Although the *diet plus exercise* group registered a significant increase in daily physical activity over the six-month period compared to *non-exercise* participants ($P<0.05$), this change was modest (25.3 ± 79.7 CPM and 5.07 ± 13.95 minutes of MVPA per day). Few *diet plus exercise* participants met the study goal

of performing an additional 150 minutes of MVPA throughout the week. Although there are relatively few studies reporting long-term effects of physical activity interventions in people with T2D, increased physical activity is notoriously difficult to maintain in the general population, but individuals with T2D report an even higher frequency of relapse (Krug et al., 1991). In a 12-month physical activity and dietary intervention involving repeated encouragement and follow-up using exercise records, Vanninen et al. (1992) reported no significant increase in physical activity or aerobic capacity in diabetic patients. Similar findings were reported by Uusitupa (1996).

Conversely, Kirk et al (2003) observed a 28% increase in accelerometer-determined physical activity over six months in adults with T2D receiving physical activity counselling, while the control group experienced a 12% decrease in physical activity. However, in a subsequent publication reporting 12-month data for the same study, increases in physical activity were not maintained and differences between baseline and 12-months did not reach statistical significance. Despite this, controls experienced a significant decrease over 12-months, resulting in the counselling group recording higher physical activity levels at both time points. Di Loreto (2003) also reported increased physical activity in 182 participants with T2D after two years of a physical activity counselling programme, compared to 158 control participants who had been referred to a diabetes outpatient diabetes centre. A seven-fold increase in self-reported physical activity was found among the intervention participants, which demonstrates the potential effectiveness of physical activity counselling in T2D.

Cardiorespiratory fitness

A low level of cardiorespiratory fitness observed in the participants of this study supports previous observations published by Regensteiner et al. (1995b) and Bjørgaas et al. (2005). This diminishment has been related to an impaired uptake of glucose into skeletal muscle blood flow (Regensteiner, Bauer and Reusch, 2005), an observation also noted in the first degree relatives of people with T2D (Thamer et al., 2003). The mean VO_{2max} value found in this present study (26.32 $ml \cdot kg \cdot min^{-1}$) is only marginally higher than the mean baseline value reported in the meta-analysis examining the effect of an exercise programme on VO_{2max} in people with T2D (22.4 $ml \cdot kg \cdot min^{-1}$) (Boulé et al., 2003), despite the latter value resulting from maximal exercise testing procedures. Furthermore, the average duration of diabetes of those participants included in the meta-analysis was 4.1 years. During baseline measurements in this study, Early ACTID participants were between five and eight months post diagnosis.

Associations between physical activity, cardiorespiratory fitness and metabolic and cardiovascular risk factors

Cross-sectional analyses in this study showed that glycaemic control was not associated with either physical activity or cardiorespiratory fitness. This finding is inconsistent with recent reports from the Look AHEAD Study, a multicentre randomised trial to determine whether participation in a lifestyle weight loss intervention can reduce the risk of cardiovascular morbidity and mortality (Look Ahead Research Group, Wadden, West et al., 2006). Analyses of baseline data from 5,145 overweight or obese individuals (mean age 58.7 years) with T2D (mean duration 6.8 years) showed that CRF, determined through maximal testing, was more strongly associated with HbA_{1c} than fatness (The Look Ahead Research Group, Wing, Jakicic et al., 2007). Relative to those in the most fit tertile, the adjusted odds ratio of having HbA_{1c} >7% for those in the least fit group was 1.44 (95% CI 1.25 to 1.67). Mean HbA_{1c} in the Look AHEAD study population was 7.3 ± 1.2%. Significant differences in HbA_{1c} of 0.23% and 0.29% were found in women and men, respectively, between the lowest and highest fitness quintile groups. Higher HbA_{1c} values and a much larger study cohort could explain the difference in findings between Look AHEAD and this present study.

Early ACTID participants with the metabolic syndrome had significantly lower levels of fitness compared to those without the syndrome (23.55 ± 7.86 vs. 28.95 ± 7.72 $ml\,kg\,min^{-1}$). This finding is consistent with recent reports from the Look AHEAD Group (Ribisl et al., 2007) and data from an earlier cross-sectional study (Carroll et al., 2000). This present study found that low physical activity and low fitness were much stronger predictors of the metabolic syndrome in women than in men. Conversely, analyses of the US NHANES data from a relatively healthy group of US adults found that the odds of the metabolic syndrome were significantly lower in moderate and high CRF categories versus the low CRF category in men only. In women there were no significant relationships between CRF and the metabolic syndrome (Brien, Janssen and Katzmarzyk, 2007).

Although physical activity was significantly associated with the metabolic syndrome, the relationship was attenuated and non-significant when fitness was also entered into the model. This attenuation has also been reported in children (Brage et al., 2004), but is inconsistent with both cross-sectional (Franks et al., 2004) and prospective data (Ekelund et al., 2005) reported from the Ely Study. The Ely study group found that physical activity energy expenditure predicted progression toward the metabolic syndrome in 605 middle-aged men and women over a period of 5.6 years, independent of aerobic fitness, obesity and other

confounding factors. Furthermore, the authors reported that VO_{2max} was not an independent predictor of the metabolic syndrome after adjustment for physical activity. The interaction between physical activity and CRF on the clustering of metabolic risk factors, which has been reported previously (Brage et al., 2004; Franks et al., 2004), was not supported by data from this present study.

5.2. Strengths and limitations of the study

5.2.1. Strengths

While many studies reporting physical activity levels in people with T2D have relied upon self-report methods, which tend only to identify leisure-time physical activity, this present study measured physical activity objectively using accelerometry. Accelerometers measure volume and intensity of all ambulatory activity, not just leisure-time activity. Compared to self-report methods, which are likely to reduce the strength of observed relationships between physical activity and health, using accelerometers offers a more precise measure of daily activity that is likely to enhance our understanding of associations with health-related outcomes.

The majority of studies reporting objectively-measured physical activity in adults with T2D involve the use of pedometers (Bjørgaas et al., 2005; Bjørgaas, Vik, Stølen et al., 2008; Tudor-Locke, Bell, Myers et al., 2003; Tudor-Locke et al., 2002a; Tudor-Locke et al., 2002b). While pedometers are able to provide more accurate data on habitual physical activity volume than questionnaires, they are not able to provide information on intensity or patterns of physical activity. Just two studies were identified that reported accelerometer data in a sample of adults with T2D (Kirk et al., 2004a; Kirk, Higgins, Hughes et al., 2001). To the author's knowledge, the present study is one of only a few to describe in detail accelerometer-determined habitual physical activity in adults with T2D.

Compliance with the physical activity measurement protocol was high, with participants wearing the accelerometer for an average of almost 16 hours per day during the measurement period. High compliance was also reflected by the number of days that the ActiGraph was worn. Eighty-two percent of participants wore the monitor for at least ten hours per day on all seven days, as requested, and a further 13.4% wore the monitor on at least six days. Consequently, at least six days of valid measurement (≥10 hours per day) was obtained from 95% of participants. It is therefore reasonable to assume that the obtained data are

representative of participants' usual physical activity levels during that period of time. Furthermore, the high rate of compliance suggests that the use of accelerometers for the requested duration was acceptable to participants in the study.

One of the major criticisms of epidemiological studies that have reported a stronger relationship between health outcomes and fitness compared to physical activity is that fitness is usually measured objectively, while physical activity assessment is often based on self-reported methods, which are imprecise and subject to error. A unique aspect of this study was the objective assessment of both cardiorespiratory fitness and physical activity. A comparison of their relationships with important health outcomes in type 2 diabetes has not been reported before.

5.2.2. Limitations

Study design

The cross-sectional nature of these analyses limits the ability to make causal conclusions. Physical activity and cardiorespiratory fitness can be both outcomes and determinants of health, and relationships between exposures and outcomes cannot be causally linked without longitudinal data. Data from good quality intervention studies are required to obtain a greater understanding of the relationships between physical activity, cardiorespiratory fitness and health-related outcomes in T2D.

Study population

The study sample was comprised of individuals who had volunteered to participate in 1-year diet plus exercise intervention that involved up to 19 visits. While volunteers where made aware that they may not be randomised to the *diet plus exercise* group, this sample is likely to represent a group of adults who were particularly motivated to diet and exercise compared to the general population of men and women with recently diagnosed T2D. It is not known whether individuals who did not participate differ from the sample studied; caution should therefore be used when generalising these findings to the wider population.

Approximately 95% of the study population were white, and the majority were well educated and of middle to upper socioeconomic status. The homogeneity of our study sample on socioeconomic characteristics may be considered a strength of the study since it reduces the likelihood of confounding by these variables. However, whether the findings apply to members of other ethnic groups or persons of low socioeconomic status remains unknown.

Physical activity measurement

Although the use of accelerometers allowed the assessment of daily physical activity volume and intensity, they are not able to measure all activities. Non-weight bearing activity, such as cycling, and walking at a pace under 1 mph are not measured well. Furthermore, participants were asked to remove the monitors when in contact with water and so water-based activities would not have recorded for participants performing these. This may have led to some participants' activity levels being underestimated. While this is a potential limitation, the ActiGraph diaries suggest that non-weight bearing activities occurred relatively infrequently, which is consistent with previously published literature (American College of Sports Medicine, 2000; Institute of European Food Studies, 1999).

Accelerometer data were examined to determine the proportion of participants engaging in recommended levels of physical activity. The Microsoft Excel macro used to reduce the raw ActiGraph data files summed the number of individual minutes of MVPA activity accumulated per day by each participant. The summed number of minutes spent in MVPA made it possible to calculate the number of participants accumulating at least 30 individual minutes of MVPA on at least five days per week, or at least 150 individual minutes per week. Since guidelines actually stipulate that the 30 minutes of moderate-intensity activity should be accumulated in bouts of at least ten consecutive minutes, the numbers reported here are likely to over estimate the number engaging in levels of activity that meet current recommendations. More sophisticated macros have since been developed, thus it would be possible to re-examine these data in future.

While collecting both accelerometer and pedometer data in a subgroup of the Early ACTID cohort could be considered a strength of this study, the accelerometer and pedometer data were not collected during the same time period. The reported association between the two measures is therefore likely to be weaker than if they had been obtained simultaneously. Although pedometer data were not collected for the purpose of examining associations with health-related outcomes, it may have been useful to ask all participants to wear a pedometer and record daily steps during the ActiGraph measurement period at baseline and six months. This would have allowed a more accurate assessment of the association between the two measures, and may also have allowed the association between reported pedometer data and health-related outcomes to be examined. In terms of interpreting the association between physical activity volume and health-related outcomes, pedometer data are perhaps more meaningful to health professionals than accelerometer counts per minute and thus may have greater potential in terms of clinical application in T2D management.

Cardiorespiratory fitness measurement

Although maximal assessment of cardiorespiratory fitness is more precise, submaximal methods were selected for this study since they were considered to be more safe and feasible for adults with T2D. While the Rockport 1-mile track walk was chosen to ensure a measure of fitness was obtained for all participants, only 70% of participants had fitness data that met the parameters of the VO_{2max} regression equation. The main reason was beta blocker medication use, which was highly prevalent in the study cohort. Furthermore, 12.6% of participants were unable to complete the 1-mile walk in less than 20 minutes, which is the cut-off for appropriate use of the regression equations to predict VO_{2max}, based on a healthy population. Compared to participants completing the distance within the required time, those unable to do so had higher BMIs, were older and less active. Musculoskeletal discomfort was the most common reason cited by participants who were unable to complete the 1-mile distance. The prevalence of musculoskeletal disorders is known to increase with both BMI and age (Department of Health, 2002; Wearing, Hennig, Byrne et al., 2006). Almost 60% of participants were obese and only 20% were under the age of 50 years.

Some participants found it hard to judge the appropriate walk speed that could be maintained for the 1-mile distance. This led to some participants walking slower than required, and some rushing in the first few laps leaving themselves unable to maintain the speed or having to stop prematurely. Regensteiner and colleagues (1995b) have previously found that, compared to women without T2D, those with the condition have a reduced maximal walking time. Slow walking paces in this study group could have led to the underestimation of VO_{2max}, which could prevent true relationships between CRF and outcome variables from being observed.

While maximal tests have been used successfully in men with T2D previously (Wei et al., 2000), participants were younger than those in the Early ACTID cohort. Furthermore, since it was not possible to obtain a valid predicted VO_{2max} value for 30% of participants using submaximal methods, it is likely that maximal testing procedures would have been inappropriate for an even greater proportion of the study population.

Health-related outcomes

Participants of this study had relatively well-controlled HbA_{1c} values, which could have reduced the ability to detect associations with different exposures. Furthermore, only 30% of participants were not prescribed

any medication. The prevalence of medication use could have obscured relationships between exposure and outcome variables.

Due to the high number of missing waist circumference values for this study population, BMI was used as a surrogate measure for central obesity. Although the IDF criteria state that central obesity can be assumed if a BMI is >30kg/m^2, waist circumference may have been a more sensitive measure in this population, which could have resulted in different individuals being classified with the metabolic syndrome. This could have influenced the observed associations between physical activity, cardiorespiratory fitness and the metabolic syndrome. Furthermore, the use of BMI as a component of the metabolic syndrome criteria means that one must be cautious when interpreting the association between the metabolic syndrome and predicted VO_{2max}, since weight is also used in the VO_{2max} estimation regression equation. It is thus possible that the strength of the association was, in part, attributable to some degree of collinearity.

Confounding factors

Confounding factors are particularly difficult to control in studies of free-living populations. While data were collected on diet, ethnicity, occupation, specific medications, smoking status, family medical history and additional health-related outcomes, such as inflammatory markers and proteinuria, these were not fully accessible at the time of analysing the data presented within this thesis. As such, associations between exposures and outcomes were not adjusted for the full range of confounders that have been cited in previously published literature. Consequently, the strength of the presented associations may have been different had all potential confounders been included in the regression models.

Since obesity is an essential component of the metabolic syndrome classification, it was not possible to control for BMI when examining the relationship between the metabolic syndrome and various exposures. BMI was found to be strongly associated with both physical activity and, of course, predicted VO_{2max}. It is therefore possible that the inverse association between physical activity, CRF and the metabolic syndrome was mediated through BMI. This could be considered a major flaw of these analyses; although it should be noted that previous studies that have been able to control for obesity in their analyses found that excluding obesity from the outcome and adjusting for it as an exposure did not significantly change the observed associations (Ekelund et al., 2005).

5.3. Implications of findings

5.3.1. Assessment of physical activity

The lack of clarity in physical activity epidemiology hinders the development of appropriate public health interventions. Objective assessment of habitual physical activity using accelerometry appears to be feasible and acceptable in adults with newly diagnosed T2D, and offers researchers the opportunity to more clearly define the relationship between physical activity and health-related outcomes in this population.

The low levels of objectively-measured physical activity found in participants of the Early ACTID cohort suggest that people with recently diagnosed T2D are a particularly inactive population group. Since participants had volunteered to participate in a long-term lifestyle intervention, it is reasonable to assume that physical activity levels in the wider population of adults with T2D will be even lower. Potentially, adults with T2D stand to benefit significantly in terms of health-related outcomes if they are to increase their activity to moderate levels. Evidence suggests that the greatest improvement in health occurs when the least active become moderately active (Haskell, 1994).

Although increases in physical activity among participants randomised to the *diet plus exercise* group were statistically significant over the six-month period (CPM 11%, time in MVPA 25%), the magnitude of change is relatively small. In light of the fact that participants received ongoing, one-to-one sessions with the study nurse that were based on behaviour change principles, the level of change emphasises the challenge facing health professionals who are responsible for facilitating physical activity adoption and maintenance in people with T2D.

5.3.2. Use of pedometers and diaries

The relatively high rate of compliance with recording self-monitored daily pedometer steps over a six-month period indicates that this is acceptable to people with recently diagnosed T2D who are attempting to increase physical activity levels. Furthermore, the fairly strong correlation between reported steps and accelerometer counts per minute suggests that pedometry may be a reasonably reliable method of determining overall physical activity volume in this population when the use of accelerometry is not possible. Thus, pedometers may offer large scale epidemiological studies a more accurate method of assessing physical activity volume compared with questionnaire-based methods and may also offer a more economical alternative to accelerometers where the intensity of activity is not required. Additionally, health

professionals could potentially use pedometers to gauge how active their patients are prior to and during physical activity counselling, thereby monitoring activity patterns, or adherence to goals, in populations where walking appears to be the most popular and acceptable form of activity.

The comparison of accelerometer and pedometer data in this study showed that participants accumulating at least 30 individual minutes of MVPA per day reported a mean daily total of just over 8000 steps, which is consistent with reports based on data from non-diabetic populations (Tudor-Locke et al., 2008). Previous literature has shown that step targets appear to be acceptable, and are perhaps more easily monitored by both patients and health professionals than time spent in moderate-intensity activity. Furthermore, step targets may be more effective than time targets for increasing activity. Indeed, a short-term intervention study showed that a target of 10000 steps per day elicited greater increases in activity compared to a target of 30 minutes per day (Hultquist, Albright and Thompson, 2005).

Step targets may also reduce the risk of compensatory physical activity behaviour. This type of behaviour can occur when individuals increase their time spent in moderate to vigorous physical activity, but reduce incidental activity throughout the day. This results in only small increases in overall physical activity volume. Some compensatory behaviour was evident in the *diet plus exercise* group of this study. While time spent in MVPA increased by 25% over the six-month period, accelerometer counts per minute increased by just 11%. This discrepancy highlights the need to emphasise the importance of ensuring that increased time spent in moderate-intensity activity is accompanied by similar increases in overall physical activity volume.

5.3.3. Cardiorespiratory fitness

The mean VO_{2max} found in this present study is not intended to be representative of all people with T2D, since the values reported are based on people volunteering for a diet plus exercise intervention. Thus, while CRF was low in the Early ACTID cohort compared to levels reported from healthy populations, it is likely that the exercise capacity in a representative sample of people with T2D would be even lower. Although it is acknowledged in the literature that people with T2D may have a genetic predisposition to low CRF, physical activity was found to be moderately associated with $VO_{2max.pred}$ within participants, suggesting that physical activity levels do have some influence in this population.

Interestingly, the relationship between $VO_{2max.pred}$ and physical activity volume (CPM) was slightly stronger than the relationship with time spent in MVPA. While it is an encouraging finding, since high-

intensity exercise may be unsuitable or not acceptable to many individuals with T2D, it would be inappropriate to infer from these data that volume is more important that intensity, since this finding is likely to be attributable to a greater spread of data for CPM than MVPA, which enhances the ability to detect associations.

5.3.4. Relationship between physical activity, cardiorespiratory fitness and health-related outcomes in type 2 diabetes

The finding that HbA_{1c} was not associated with either physical activity or CRF is inconsistent with previous research and these relationships require further investigation for the purpose of translation into policy and practice recommendations. The present study found that low levels of physical activity and CRF were independently predictive of the metabolic syndrome. The crude odds ratios reported in this thesis suggest that the difference in odds of the metabolic syndrome between quartiles of activity volume and time spent in MVPA is greatest between the least active and next active group. This provides support to suggestions that the greatest potential gain in public health could be achieved by those who are least active becoming moderately active.

The apparent protective effect of physical activity and CRF appears to be much greater in women. Women feature less often than men in studies examining relationships between physical activity, fitness and health-related outcomes, and it is suggested that gender differences are examined in future studies as findings may prove useful in planning, targeting and evaluating interventions.

In light of the findings reported in this thesis, and also the increasing body of evidence showing that higher levels of physical activity and CRF are associated with a lower risk of mortality in people with T2D, it is felt that physical activity should be strongly promoted in diabetes care. Indeed there is no evidence to suggest that physical activity could be harmful in diabetes management, and thus, it should also be promoted as an adjunct to pharmacological treatment.

5.4. Conclusions and recommendations for future research and practice

To the author's knowledge, this is one of the few studies to describe in detail objectively-measured habitual physical activity in adults with T2D. Furthermore, it is the first study to investigate the relative importance of objectively measured physical activity and cardiorespiratory fitness in relation to metabolic and physiological outcomes in type 2 diabetes.

The excellent compliance with accelerometers demonstrated in this study highlights the feasibility for assessing habitual physical activity objectively in this population, and thus it should be utilised more extensively in the future. Despite this study group consisting of adults volunteering for a diet and exercise intervention, objectively measured physical activity levels were well below the recommended 30 minutes of moderate-intensity activity on most days of the week. This emphasises the need to increase physical activity in people with T2D and in particular those who are obese.

The magnitude of increased physical activity observed among participants in the *diet plus exercise* group over a six-month period is relatively small. The discrepancy between increases in time spent in MVPA and overall volume of activity among these participants suggests that compensatory behaviour may have taken place. More focus on strategies for facilitating and promoting the adoption of physical activity, without compensatory behaviour, and optimising maintenance of increased activity in people with T2D should be prioritised in future research.

Cardiorespiratory fitness (CRF) levels were also very low in this study population. A moderate association was found between physical activity and CRF, whereby the most active tended to have higher levels of fitness compared to the least active. Interestingly, CRF was more strongly related to physical activity volume than time spent in moderate to vigorous physical activity, although this may be a function of the differences in the spread of data between the two activity dimensions, rather than a reflection of the true associations. A further finding was that physical activity appeared to explain a much greater proportion of the variance in CRF in women than men.

Although this study found no evidence that glycaemic control was associated with either physical activity or CRF, both were predictors of the metabolic syndrome, defined according to IDF criteria. These predictors were stronger in women than in men. When physical activity and CRF were compared, CRF was

a stronger predictor. The apparent stronger association between the metabolic syndrome and physical activity and fitness in women than in men is interesting and justifies further exploration.

While this study does not prove a causal pathway between physical activity, fitness and the metabolic syndrome in T2D, these data suggest that people with recently-diagnosed diabetes, and in particular women, may benefit from regular physical activity and higher levels of fitness. In contrast to previous research, the lack of an association between glycaemic control and habitual physical activity or CRF found in this study highlights the need for larger studies to assess these relationships more fully.

Randomised controlled trials are recommended for determining the relative importance of physical activity and CRF in the aetiology of T2D and whether modifiable factors, such as CRF, influence the magnitude of response in metabolic and physiological outcomes to increased exercise in this clinical population. Understanding these relationships more fully would inform future interventions.

The high compliance with using pedometers and recording self-monitored physical activity over a six-month period indicates that these are acceptable to people with recently diagnosed T2D who are attempting to change physical activity behaviour. Furthermore, the fairly strong correlation between reported steps and accelerometer counts per minute suggests that pedometry may be a reasonably reliable method of determining overall physical activity volume in this population. Participants accumulating 30 minutes of at least moderate-intensity activity reported accumulating just over 8000 steps per day. This is consistent with previous reports in people with T2D and thus may have useful applications in clinical practice.

Studies using valid and reliable objective measures of physical activity are becoming more widespread, but they appear to be underused in people with diabetes. This study opens the door for future research to further explore the relationships between objectively-determined physical activity, CRF and health-related outcomes in type 2 diabetes. Accurate quantification of exposures and outcomes enables true relationships to be assessed. Identification of these relationships is essential for the development of policy and practice recommendations relating to the use of physical activity in the management of diabetes.

The findings outlined in this thesis can be translated into a number of recommendations for practice which are highlighted below.

- Pedometers and self-reported steps correlate well with accelerometers and offer a reasonable assessment of a patient's overall physical activity volume.

- Pedometers and diaries appear to be acceptable to patients with type 2 diabetes and may be a useful means of facilitating physical activity adoption and maintenance.

- Negotiating step goals with patients rather than time-based goals, e.g. 3000 extra steps vs. 30 extra minutes, may lower the risk of compensatory behaviour, whereby an increase in structured activity can sometimes be accompanied by a reduction in overall physical activity volume.

- Recommending a walking pace of 1000 steps per 10 minutes is reasonable for people with type 2 diabetes and offers a useful indication of 'brisk' walking for this population. Patients in the present study reported that this was a useful message.

- Adults with type 2 diabetes accumulating <8000 steps/day are unlikely to be meeting the recommended 30 minutes of moderate-intensity activity. Thus, patients should be encouraged to accumulate >8000 steps on most days.

- Physical activity levels decline with each increasing BMI category and morbidly obese patients are likely to be the most sedentary. Differences in physical activity levels between BMI groups are greatest at the weekend. This may be a useful time for patients to consider increasing their physical activity.

- The present study found that physical activity volume was associated with cardiorespiratory fitness. Both of these were independently associated the metabolic syndrome. It may be useful, therefore, to emphasise the importance of increasing the volume of physical activity in patients with type 2 diabetes before focusing on intensity.

- The greatest reduction in risk of the metabolic syndrome was apparent between the two lowest physical activity and fitness quartile groups. A further reduction in risk was seen with each increasing quartile group. Accordingly, the greatest public health benefit may occur when the most sedentary become moderately active.

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Appendices

Appendix 1. List of abbreviations and acronyms

$\%HR_{max}$	Percentage of predicted maximum heart rate
1-MTW	1-mile track walk submaximal fitness test
ACLS	Aerobics Center Longitudinal Study
BMI	Body mass index
CI	Confidence interval
CRF	Cardiorespiratory fitness
CT	Controlled trial
DPP	Diabetes Prevention Program
Early ACTID	**Early Activity In Diabetes**
FPG	Fasting plasma Glucose
HbA_{1c}	Glycated haemoglobin
HDL cholesterol	High-density lipoprotein cholesterol
HR	Heart rate
IFG	Impaired fasting glucose (pre-diabetic condition)
IGT	Impaired glucose tolerance (pre-diabetic condition)
LDL cholesterol	Low-density lipoprotein cholesterol
MET	Metabolic equivalent
MVPA	Moderate to vigorous physical activity
NICE	National Institute of Health and Clinical Excellence
NIDDM	Non-insulin dependent diabetes mellitus
NS	Non-significant
OGTT	Oral glucose tolerance test
OR	Odds Ratio
PA	Physical activity
PAEE	Physical activity energy expenditure
PRF	Participant-held record file
RCT	Randomised controlled trial
RPE	Rating of perceived exertion
RPG	Random plasma glucose
RR	Relative risk
SOP	Standard operating procedure
SD	Standard deviation
SPSS	Statistical Package for Social Science
T2DM	Type 2 diabetes mellitus
TEE	Daily total energy expenditure
TC	Total cholesterol
TG	Triglycerides
UKPDS	UK Prospective Diabetes Study
VO_{2max}	Maximal oxygen uptake
$VO_{2max.pred}$	Predicted maximal oxygen uptake
WHO	World Health Organization

Appendix 2. Co-investigators of the Early ACTID Study

Name	Title
Dr Rob Andrews	**Trial Principal Investigator;** Consultant senior lecturer in Exercise, Diabetes and Endocrinology
Dr Ashley Cooper	Head of Department, Exercise, Nutrition and Health Sciences; Senior Lecturer in Exercise, Nutrition and Health Sciences
Dr Alan Montgomery	Senior Lecturer in Primary Care Research
Professor Tim Peters	Professor of Primary Care Health Services Research
Professor Debbie Sharp	Professor of Primary Health Care
Dr Colin Dayan	Consultant Senior Lecturer in Diabetes and Endorinology; URCN Head of Clinical Research

Appendix 3. Gantt chart for PhD

Task	2004		2005												2006												2007												2008									
	N	D	J	F	M	A	M	J	J	A	S	O	N	D	J	F	M	A	M	J	J	A	S	O	N	D	J	F	M	A	M	J	J	A	S	O	N	D	J	F	M	A	M	J	J	A	S	O
Development of draft participant record materials (PRF)																																															
Courses related to PhD																																															
Pilot PRF materials																																															
Development of SOP																																														
Provision of nurse training and refresher sessions focused on delivering the activity intervention								11	18 & 19	9				8	12		23	12		8					14			22																			
Conference contributions related to PhD work																																														
Finalise and professionally print PRF materials																																														
Development of participant information sheets relating to the assessment of physical activity and CRF																																														
Development of measurement protocols and data-collection tools relating to physical activity and cardiorespiratory fitness (CRF) assessments																																														
Development of data collection sheets																																														
Development of database for assessing adherence to physical activity goals																																														
CRF & PA measurements																																														
Preparation of upgrade document																																														
Upgrade																																														
Data cleaning and analyses																																														
Writing up																																														

Appendix 4. Literature search terms and strategy

ELECTRONIC SEARCH TERMS

Type 2 diabetes mellitus

1. type 2 diabetes.tw.
2. type II diabetes.tw.
3. Adult onset diabetes.tw.
4. niddm.tw.
5. non-insulin dependent diabetes.tw.
6. metabolic syndrome.tw.
7. syndrome x.tw.
8. 1 or 2 or 3 or 4 or 5 or 6 or 7

Physical activity

9. physical activity.tw
10. exercise.tw.
11. training.tw.
12. walking.tw
13. cycling.tw.
14. aerobic.tw.
15. pedomet$
16. 9 or 10 or 11 or 12 or 13 or 14 or 15

Cardiorespiratory fitness

17. fitness.tw.
18. aerobic capacity.tw.
19. exercise capacity.tw.
20. VO_{2}.tw.
21. 17 or 18 or 19 or 20

Behaviour change

22. adopti$.tw
23. initiat$.tw.
24. behaviour.tw.
25. behavior.tw
26. promot$.tw
27. barrier$.tw
28. motivate$.tw
29. chang$.tw
30. counsel$.tw
31. consult$.tw
32. 22 or 23 or 24 or 25 or 27 or 27 or 28 or 29 or 30 or 31

COMBINED SEARCHES

'Type 2 diabetes mellitus' AND 'physical activity'

33. 8 and 16

'Type 2 diabetes mellitus' AND 'cardiorespiratory fitness'

34. 8 and 21

'Type 2 diabetes mellitus' AND 'physical activity' AND 'cardiorespiratory fitness'

35. 8 and 16 and 21

'Physical activity' AND 'behaviour change'

36. 16 and 32

tw., text word; $, any character(s)

Appendix 5. List of materials developed by the researcher for the participant-held record file (PRF)

VISIT	SECTION	INSERT	UC	D	D + E
3	**INFORMATION**	**SECTION DIVIDER & CONTENTS**	✓	✓	✓
3	Personal	SUB-SECTION FRONT PAGE	✓	✓	✓
3		Welcome & contact details	✓	✓	✓
3		Medication	✓	✓	✓
3		Early ACTID goals	✓	✓	✓
4		Introducing your Early ACTID group: Control	✓	-	-
4		Introducing your Early ACTID group: Healthy Eating	-	✓	-
4		Introducing your Early ACTID group: Healthy Eating and Physical Activity	-	-	✓
4		Early ACTID group goals: Healthy eating	-	✓	-
4		Early ACTID group goals: Healthy Eating and Physical Activity	-	-	✓
5		Working together as a team	-	✓	✓
3	Appointments	SUB-SECTION FRONT PAGE	✓	✓	✓
4		Appointments: Control	✓	-	-
4		Appointments: Intervention groups	-	✓	✓
4		Appointment overview (Control)	✓	-	-
4		Appointment overview (Diet only)	-	✓	-
4		Appointment overview: (Diet + exercise)	-	-	✓
3	Glossary	SUB-SECTION FRONT PAGE	✓	✓	✓
3		Glossary of terms	✓	✓	✓
3/5	**HEALTHY EATING**	**SECTION DIVIDER AND CONTENTS**	✓	✓	✓
3	**Keeping track**	SUB-SECTION FRONT PAGE	✓	✓	✓
3		Recording your food intake with a diary	✓	✓	✓
3		Food diary: Sample	-	✓	✓
5		Recording your weight	-	✓	✓
5		Recording your weight on a graph	-	✓	✓
3	**Diary**	SUB-SECTION FRONT PAGE	✓	✓	✓
3		Diary: Intervention	✓	✓	✓
3		Food and food associations	✓	✓	✓
3	**Goals and plans**	SUB-SECTION FRONT PAGE	✓	✓	✓
4		Goal setting	-	✓	✓
4+		Weight loss goals & Areas to focus on - agreed with your dietitian	-	✓	✓
5+		Healthy eating goals & Successes/difficulties	-	✓	✓
3	**Information sheets**	SUB-SECTION FRONT PAGE	✓	✓	✓
4		Introduction to healthy eating principles (Control)	✓	-	-
4		Introduction to healthy eating principles (Diet only; Diet + exercise)	-	✓	✓
4		Introduction weight control/loss & Key points	-	✓	✓
5		Reviewing your food diary & Changing eating behaviours	-	✓	✓
5		Setting goals	-	✓	✓
6		Healthy eating part II	-	✓	✓
7		Triggers and cues for eating & Key points	-	✓	✓
8		Relapses	-	✓	✓
8		Difficult situations & Key points	-	✓	✓
9		Portion sizes	-	✓	✓
9		Food labels & Key points	-	✓	✓
10		Eating habits & Key points	-	✓	✓
13		Preparing and cooking food	-	✓	✓
13		Holidays, eating out and special occasions & Setting goals & key points	-	✓	✓
14		Alcohol & Key points	-	✓	✓
15		Recap of healthy eating & weight control	-	✓	✓
16		Eating on the go - Healthier snacking & Key points	-	✓	✓
19		Sources of information	-	✓	✓

UC, usual care; D, diet only, D + E, Diet plus exercise.

VISIT	SECTION	INSERT	UC	D	D + E
5	**PHYSICAL ACTIVITY**	**SECTION DIVIDER & CONTENTS**	-	-	✓
5	Keeping track	SUB-SECTION FRONT PAGE	-	-	✓
5		Pedometers	-	-	✓
5		Recording your physical activity with a diary	-	-	✓
5		Physical activity diary: Sample	-	-	✓
5		Recording your physical activity on a graph	-	-	✓
5	Diary	SUB-SECTION FRONT PAGE	-	-	✓
5		Diary	-	-	✓
5	Goals and plans	SUB-SECTION FRONT PAGE	-	-	✓
6		Setting physical activity goals	-	-	✓
6		Other brisk activities	-	-	✓
5+		Physical activity goals	-	-	✓
5+		Physical activity plan	-	-	✓
5	Information sheets	SUB-SECTION FRONT PAGE	-	-	✓
5		Trouble shooting your pedometer	-	-	✓
6		Facts about walking	-	-	✓
6		Staying safe: Foot care	-	-	✓
6		Staying safe: Prevention and Illness	-	-	✓
6		Staying safe: Hypos	-	-	✓
6		Staying safe: Stretching	-	-	✓
5	Gaining confidence	SUB-SECTION FRONT PAGE	-	-	✓
6		Physical activity history	-	-	✓
6		Benefits of physical activity and Pros & Cons	-	-	✓
7		Lifestyle activity	-	-	✓
7		Opportunities to be active	-	-	✓
8		Preventing relapses	-	-	✓
7+		Barriers to physical activity*	-	-	✓
7+		Personal time diary*	-	-	✓
7+		People to help you achieve your goals*	-	-	✓
7+		Local exercise opportunities*	-	-	✓
3	**PROGRESS REPORTS**	**SECTION DIVIDER & CONTENTS**	✓	✓	✓
3		General health record	✓	✓	✓
5		Weight chart	-	✓	✓
5		Weight graph	-	✓	✓
5+		Physical activity graph	-	-	✓
17/19		Reviewing your progress & planning ahead	✓	✓	✓
3	**PERSONAL NOTES**	**SECTION DIVIDER & CONTENTS**	✓	✓	✓
3		Personal notes	✓	✓	✓

UC, usual care; D, diet only, D + E, Diet plus exercise; * Optional materials used to address perceived barriers to physical activity

Appendix 6. Participant Record File inserts developed by the researcher

INFORMATION

INFORMATION: CONTENTS

EARLY ACTID

INFORMATION

Personal

INFORMATION: Personal

Welcome

Welcome to the Early ACTID study. This is your personal diabetes record file, which has been developed to support you in managing your diabetes, with the help of your Early ACTID nurse, dietitian and doctor.

At each visit with the nurse and dietitian, you will be given handouts to keep in this file. Some of the handouts contain information only, whilst others may involve short tasks. Your nurse and dietitian will assist with these tasks, which have been designed to help you review your progress, and think about how best to manage your diabetes.

As part of your programme, you will be asked to keep records of your eating habits and activity levels. It is important that you complete these honestly, so that we can help you as best as possible.

Please complete all the relevant details, or ask the nurse to do so for you.

This record file is an important part of your Early ACTID programme.

PLEASE BRING IT TO ALL YOUR APPOINTMENTS WITH THE NURSE AND DIETITIAN.

Continued overleaf

Contact details

Your name: _____

Early ACTID ID number: _____

GP name: _____

Address: _____

Telephone number: _____

Early ACTID nurse (Primary contact): _____

Telephone number: _____

Email: _____

Pager number: _____

Early ACTID dietitian: _____

Telephone number: _____

Early ACTID doctor: _____

Date started	Medication	Strength	How many/when	Purpose	Date stopped

Continued overleaf

INFORMATION: Personal

Date started	Medication	Strength	How many/when	Purpose	Date stopped

Early ACTID goals

Your Early ACTID goals will be to:

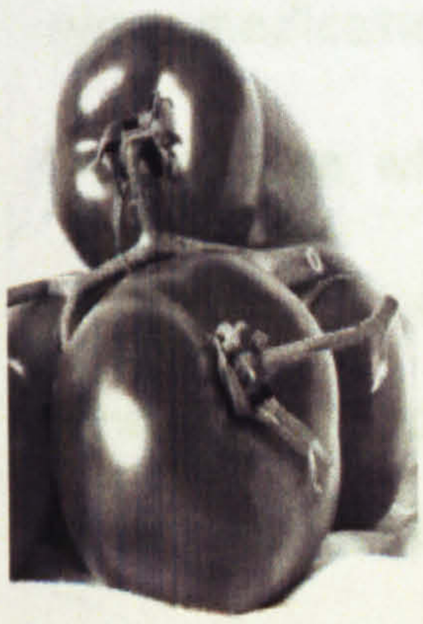
1. eat healthily,

2. take regular exercise,

3. take any medication that is prescribed for you, and

4. attend all of your appointments.

We will help you reach your goals



INFORMATION: Personal

Introducing your Early ACTID group

EARLY ACTID

The healthy eating and physical activity group

You have been randomised to the **HEALTHY EATING AND PHYSICAL ACTIVITY GROUP**, which is one of three groups in the Early ACTID study. In this group, the focus is on **making healthy food choices** and **increasing daily physical activity** to try and manage your diabetes and prevent complications.

In this programme, we will help you:

- change your eating habits and physical activity levels for the long term,
- improve your diabetes control,
- improve your general health,
- achieve worthwhile weight loss, and
- maintain the weight loss.

During this programme you will see the following diabetes specialists:

- A **doctor**, who will take a medical history, examine you, and look after your medication.
- A **dietitian**, who will give you advice about healthy eating.
- A **nurse**, who will take your measurements, discuss your diabetes treatment and support you in making healthy changes to your eating patterns and level of physical activity.

In total, you will see us on 19 occasions.

INFORMATION: Personal

Continued overleaf

Introducing your Early ACTID group continued

Making lifestyle changes to help control your diabetes and your weight can be difficult. Lifestyle habits are formed over many years and changing these for good takes a lot of effort.

What will you learn?

This programme emphasises the need to make long-term changes to your eating habits and physical activity patterns. The information provided during your appointments will be tailored to your individual needs, but is likely to include:

Healthy Eating	Physical activity
• Healthy eating principles and the benefits for diabetes • Why weight control is important for health • How to read food labels • Shopping and cooking tips • How to overcome your personal barriers to healthy eating • How to prevent relapses	• The benefits of physical activity for health • How to monitor and record your physical activity • How to create opportunities to be active • How to overcome your personal barriers to physical activity • How to prevent relapses

Your success with this programme will depend on how committed you are, and how much you want to change and take control of your health.

Continued overleaf

Healthy eating & physical activity group goals

Your specific long-term HEALTHY EATING goals will be to:

1. Understand what healthy eating is and the benefits for diabetes.

2. Understand what factors contribute to overweight and obesity.

3. Adopt a healthy approach towards food and eating.

4. Lose 5-10% of your starting body weight within the first 6 months.

5. Maintain this weight loss for the second 6 months.

Your healthy eating goals are NOT to:

1. Make drastic dietary changes.

2. Achieve an unrealistic "ideal weight".

3. Lose weight for short term goals such as a special occasion.

Your specific long-term PHYSICAL ACTIVITY goal will be to:

1. Do 30 minutes of brisk walking (or an appropriate alternative) on five days of the week, OVER AND ABOVE what you were doing when you entered the study. This amounts to an EXTRA 2 ½ hours each week.

Continued overleaf

Healthy eating and physical activity goals continued

Your long-term goals are safe and realistic, and can be achieved by making gradual changes to your eating habits. Reaching these goals can help you:

- control your diabetes, and may reduce the need for medication;
- reduce your risk of complications in the future;
- control your weight;
- lower blood pressure and improve cholesterol;
- feel better and more healthy in general.

We will help you reach your goals

Working together as a team

Your nurse will:

- ❑ Answer your questions
- ❑ Look at your keeping track records during your appointments
- ❑ Acknowledge what you are doing well and identify difficulties
- ❑ Support and help you reach your goals
- ❑ Be honest and realistic
- ❑ Other_____
- ❑ Other_____

Continued overleaf

Working together as a team continued

Your nurse will ask you to:

- ❑ Come to appointments and bring your record file
- ❑ Call in advance if you are going to miss an appointment
- ❑ Do your best to reach your goals
- ❑ Keep track
- ❑ Let them know if you have any problems
- ❑ Be honest and realistic
- ❑ Other _____
- ❑ Other _____

We agree to work together in the ways described above:

Participant's signature _____

Nurse's signature _____

EARLY ACTID

INFORMATION

Appointments

INFORMATION: Appointments

Time (Wks)	Visit	Appointment	Date	Time	Location
0	4	Doctor			
		Dietitian			
2	5	Nurse			
4	6	Dietitian			
		Nurse			
6	7	Nurse			
8	8	Nurse			
10		Nurse telephone call			
14	9	Dietitian			
		Nurse			
20	10	Nurse			
26	11	Fitness assessment			

Continued overleaf

INFORMATION: Appointments

Time (Wks)	Visit	Appointment	Date	Time	Location
28	12	Nurse			
32	13	Doctor			
		Dietitian			
		Nurse			
38	14	Nurse			
42	15	Dietitian			
		Nurse			
46	16	Nurse			
52	17	Fitness assessment			
54	18	Nurse			
58	19	Doctor			
		Dietitian			

Appointment overview

During the course of this programme, you will be learning about different aspects of diabetes, diet, physical activity and lifestyle change. At each visit, you will be introduced to new topics, and you will receive new handouts to keep in your file. At the end of each visit, you will set yourself new short-term goals for the following weeks until your next appointment.

At each session, there will be time for you to ask any questions that you may have. If you have any concerns between your visits, you may contact the nurse for advice.

The table overleaf outlines the focus of each appointment during the study.

Continued overleaf

Appointment overview

Wks	Visit	Appointment	Focus
-6	1	Nurse	• Consent and screening
-4	2	Fitness	• Baseline fitness assessment • ActiGraph monitor, diary and questionnaires
-2	3	Nurse	• Consent and baseline measurements • Record file • Food and sleep diaries
0	4	Doctor	• Baseline review
		Dietitian	• Randomisation • Overview of intervention • Healthy eating and diabetes (part 1) • Introduction to weight loss and control • Areas to focus on and weight loss targets
2	5	Nurse	• Changing eating behaviours • Setting realistic goals • Keeping track of your weight • Food diary
			• Keeping track of your physical activity
4	6	Dietitian	• Healthy eating (part 2: Carbohydrate and fats)
		Nurse	•
			• Setting physical activity goals • Your physical activity history • Benefits of physical activity
6	7	Nurse	• Identifying and dealing with triggers/cues for eating
			• Lifestyle physical activity

Continued overleaf

Appointment overview

Wks	Visit	Appointment	Focus
8	8	Nurse	• Relapses and coping with difficult situations • Food diary
			• Relapses and coping with difficult situations
14	9	Dietitian	• Portion sizes • Understanding food labels
		Nurse	•
			• Overcoming barriers to physical activity
20	10	Nurse	• Eating and shopping habits
			• Maintaining change
26	11	Fitness	• 6-month fitness assessment • ActiGraph monitor, diary and questionnaires
28	12	Nurse	• 6-month measurements • Food and sleep diaries
32	13	Doctor	• 6-month review
		Dietitian	• Preparing and cooking food • Holidays • Eating out and special occasions
		Nurse	•
			• Maintaining change
38	14	Nurse	• Alcohol • Food diary
			• Maintaining change
42	15	Dietitian	• Review healthy eating and weight control
		Nurse	•
			• Maintaining change

Continued overleaf

Appointment overview

Wks	Visit	Appointment	Focus
46	16	Nurse	• Healthy eating on the go • Maintaining change
52	17	Fitness	• 12-month fitness assessment • ActiGraph monitor, diary and questionnaires
54	18	Nurse	• 12-month measurements • Food and sleep diaries • Maintaining change
58	19	Doctor	• 12-month review • Discharge plan
		Dietitian	• Maintaining dietary change and weight control • Discharge plan

EARLY ACTID

INFORMATION

Glossary

Glossary of terms

Here are some words that you may come across when reading about diabetes. This is for your information only, and it is not necessary to know what all the words mean.

Acute - describes something that happens suddenly and for a short time. Opposite of ***chronic***.[1]

Adipocytes - fat cells.[2]

Albumin: Creatinine - this ratio is a useful measure of renal function and is measured using an early morning urine sample.

Albuminuria - a condition in which the ***urine*** has more than normal amounts of a ***protein*** called albumin. Albuminuria may be a sign of ***nephropathy*** (Kidney disease).[1]

Alpha cells - a type of cell in the ***pancreas***. Alpha cells make and release a ***hormone*** called ***glucagon***. The body sends a signal to the alpha cells to make glucagon when ***blood glucose*** falls too low. Then glucagon reaches the ***liver*** where it tells it to release ***glucose*** into the blood for energy.[1]

Alpha-glucosidase inhibitor - a class of oral medicine for ***type 2 diabetes*** that blocks ***enzymes*** that digest ***starches*** in food. The result is a slower and lower rise in ***blood glucose*** throughout the day, especially right after meals. (Generic names: acarbose and miglitol.)[1]

Antibodies - ***proteins*** made by the body to protect itself from "foreign" substances such as bacteria or viruses. People get ***type 1*** diabetes when their bodies make antibodies that destroy the body's own ***insulin***-making ***beta cells***.[1]

Antigen - a molecule found either inside or on the surface of a cell that can induce an immune response by stimulating the production of antibodies. Antigens are used by the body's immune system to recognise whether the cell is a dangerous foreign intruder or a harmless part of the body. They are like molecular labels.[2]

Arteries - large ***blood vessels*** that carry blood with oxygen from the heart to all parts of the body.[1]

Arteriosclerosis - hardening of the ***arteries***.[1]

Glossary of terms

Atherosclerosis - clogging, narrowing, and hardening of the body's large ***arteries*** and medium-sized ***blood vessels***. Atherosclerosis can lead to ***stroke***, heart attack, eye problems, and ***kidney*** problems.[1]

Autoimmune - disorder of the body's ***immune system*** in which the immune system mistakenly attacks and destroys body tissue that it believes to be foreign.[1]

Autonomic neuropathy - a type of ***neuropathy*** affecting the lungs, heart, stomach, intestines, bladder, or genitals.[1]

Beta cells - a cell that makes ***insulin***. Beta cells are located in the ***islets*** of the ***pancreas***.[1]

Biguanide - a class of oral medicine used to treat ***type 2 diabetes*** that lowers ***blood glucose*** by reducing the amount of ***glucose*** produced by the ***liver*** and by helping the body respond better to ***insulin***. (Generic name: metformin.)[1]

Blood glucose - the main ***sugar*** found in the blood and the body's main source of energy. Also called blood sugar.[1]

Blood glucose levels - the amount of ***glucose*** in a given amount of blood. It is noted in millimoles per litre, or ***mmol/l***.[1]

Blood pressure - the force of blood exerted on the inside walls of ***blood vessels***. Blood pressure is expressed as a ratio (example: 120/80, read as "120 over 80"). The first number is the systolic pressure, or the pressure when the heart pushes blood out into the ***arteries***. The second number is the diastolic pressure, or the pressure when the heart rests.[1]

Blood vessels - tubes that carry blood to and from all parts of the body. The three main types of blood vessels are ***arteries***, ***veins***, and ***capillaries***.[1]

Body Fat percentage - the proportion of a person's body that is fat.

Body mass index (BMI) - a measure used to evaluate body weight relative to a person's height. BMI is used to find out if a person is underweight, normal weight, overweight, or obese.[1]

Calories - a unit representing the energy provided by food. ***Carbohydrate***, ***protein***, ***fat***, and alcohol provide calories in the diet. Carbohydrate and protein have 4 calories per gram, fat has 9 calories per gram, and alcohol has 7 calories per gram.[1]

Continued overleaf

Glossary of terms

Carbohydrate - one of the three main nutrients in food. Foods that provide carbohydrate are ***starches***, vegetables, fruits, dairy products, and ***sugars***.[1]

Cardiovascular disease - disease of the heart and ***blood vessels*** (***arteries***, ***veins***, and ***capillaries***).[1]

Cerebrovascular disease - damage to ***blood vessels*** in the brain. Vessels can burst and bleed or become clogged with fatty deposits. When blood flow is interrupted, brain cells die or are damaged, resulting in a ***stroke***.[1]

Cholesterol - a type of ***fat*** produced by the ***liver*** and found in the blood; it is also found in some foods. Cholesterol is used by the body to make ***hormones*** and build cell walls.[1]

High density lipoprotein (HDL) cholesterol - a ***fat*** found in the blood that takes extra ***cholesterol*** from the blood to the ***liver*** for removal. Sometimes called "good" cholesterol.[1]

Low density lipoprotein (LDL) cholesterol - a ***fat*** found in the blood that takes ***cholesterol*** around the body to where it is needed for cell repair and also deposits it on the inside of ***artery*** walls. Sometimes called "bad" cholesterol.[1]

Total cholesterol - the total amount of cholesterol carried in the blood.

Chronic - describes something that is long-lasting. Opposite of ***acute***.[1]

Complications - harmful effects of diabetes such as damage to the eyes, heart, ***blood vessels***, nervous system, teeth and gums, feet and skin, or ***kidneys***. Studies show that keeping ***blood glucose***, ***blood pressure***, and ***low-density lipoprotein cholesterol*** levels close to normal can help prevent or delay these problems.[1]

Creatinine - a waste product from ***protein*** in the diet and from the muscles of the body. Creatinine is removed from the body by the ***kidneys***; as kidney disease progresses, the level of creatinine in the blood increases.[1]

C-reactive protein (CRP) - a protein present in blood serum in various abnormal states (as inflammation).

Diabetes mellitus - a condition characterized by ***hyperglycaemia*** resulting from the body's inability to use ***blood glucose*** for energy. In ***type 1 diabetes***, the ***pancreas*** no longer makes ***insulin*** and therefore blood glucose cannot enter the cells to be used for energy. In ***type 2 diabetes***, either the pancreas does not

make enough insulin or the body is unable to use insulin correctly.[1]

Diabetes nurse - health professional specialising in the education and support of patients with diabetes.

Diabetic ketoacidosis (DKA) - an emergency condition in which extremely high ***blood glucose levels***, along with a severe lack of ***insulin***, result in the breakdown of body ***fat*** for energy and an accumulation of ***ketones*** in the blood and ***urine***. Signs of DKA are nausea and vomiting, stomach pain, fruity breath odour, and rapid breathing. Untreated DKA can lead to ***coma*** and death.[1]

Diabetic retinopathy - diabetic eye disease; damage to the small ***blood vessels*** in the ***retina***. Loss of vision may result.[1]

Diabetologist - a doctor who specializes in treating people who have diabetes.[1]

Dialysis - the process of cleaning wastes from the blood artificially. This job is normally done by the ***kidneys***. If the kidneys fail, the blood must be cleaned artificially with special equipment. The two major forms of dialysis are haemodialysis and peritoneal dialysis.[1]

Haemodialysis - the use of a machine to clean wastes from the blood after the kidneys have failed. The blood travels through tubes to a dialyser, a machine that removes wastes and extra fluid. The cleaned blood then goes back into the body.[1]

Dietitian - a health care professional who advises people about meal planning, weight control, and diabetes management. A registered dietitian (RD) has more training.[1]

D-phenylalanine derivative - a class of oral medicine for ***type 2 diabetes*** that lowers ***blood glucose levels*** by helping the ***pancreas*** make more ***insulin*** right after meals. (Generic name: nateglinide.)[1]

Endocrine gland - a group of specialized cells that release ***hormones*** into the blood. For example, the ***islets*** in the ***pancreas***, which secrete ***insulin***, are endocrine glands.[1]

Endocrinologist - a doctor who treats people who have ***endocrine gland*** problems such as diabetes.[1]

Enzyme - *protein* made by the body that brings about a chemical reaction, for example, the enzymes produced by the gut to aid digestion.[1]

Continued overleaf

Glossary of terms

Erectile dysfunction - See impotence.[1]

Fasting blood glucose test - a check of a person's ***blood glucose level*** after the person has not eaten for 8 to 12 hours (usually overnight). This test is used to diagnose ***pre-diabetes*** and diabetes. It is also used to monitor people with diabetes.[1]

Fat - 1. One of the three main nutrients in food. Foods that provide fat are butter, margarine, salad dressing, oil, nuts, meat, poultry, fish, and some dairy products. 2. Excess ***calories*** are stored as body fat, providing the body with a reserve supply of energy and other functions.[1]

Glomerulus - a tiny set of looping ***blood vessels*** in the ***kidney*** where the blood is filtered and waste products are removed.[1]

Glucagon - a ***hormone*** produced by the ***alpha cells*** in the ***pancreas***. It raises ***blood glucose***. An injectable form of glucagon, available by prescription, may be used to treat severe ***hypoglyaemia***..[1]

Glucose - One of the simplest forms of sugar.[1]

Glycaemic index - a ranking of ***carbohydrate***-containing foods, based on the food's effect on ***blood glucose*** compared with a standard reference food.[1]

Glycogen - the form of ***glucose*** found in the ***liver*** and muscles.[1]

Glycosuria - the presence of ***glucose*** in the ***urine***.[1]

Glycosylated haemoglobin (HBA1C) - a test that measures a person's average blood glucose level over the past 2 to 3 months. The test shows the amount of glucose that sticks to the red blood cell, which is proportional to the amount of glucose in the blood.[1]

Haemoglobin - the part of a red blood cell that carries oxygen throughout the body.[1]

Heart attack - see ***myocardial infarction***.

Hormone - a chemical produced in one part of the body and released into the blood to trigger or regulate particular functions of the body. For example, ***insulin*** is a hormone made in the ***pancreas*** that tells other cells when to use ***glucose*** for energy. Synthetic hormones, made for use as medicines, can be the same or different from those made in the body.[1]

Glossary of terms

Hyperglycaemia - excessive ***blood glucose***. Fasting hyperglycaemia is blood glucose above a desirable level after a person has fasted for at least 8 hours. Postprandial hyperglycaemia is blood glucose above a desirable level 1 to 2 hours after a person has eaten.[1]

Hyperinsulinaemia - a condition in which the level of ***insulin*** in the blood is higher than normal. Caused by overproduction of insulin by the body. Related to ***insulin resistance***.[1]

Hyperlipidaemia - higher than normal ***fat*** and ***cholesterol*** levels in the blood.[1]

Hypertension - a condition present when blood flows through the ***blood vessels*** with a force greater than normal. Also called high ***blood pressure***. Hypertension can strain the heart, damage blood vessels, and increase the risk of heart attack, ***stroke***, ***kidney problems***, and death.[1]

Hypoglycaemia (Hypo) - a condition that occurs when one's ***blood glucose*** is lower than normal, usually lower than 4 ***mmol/l***. Signs include hunger, nervousness, shakiness, perspiration, dizziness or light-headedness, sleepiness, and confusion. If left untreated, hypoglycaemia may lead to unconsciousness. Hypoglycaemia is treated by consuming a ***carbohydrate***-rich food such as a ***glucose tablet*** or juice. It may also be treated with an ***injection*** of ***glucagon*** if the person is unconscious or unable to swallow. Also called an ***insulin reaction***.[1]

Hypotension - low ***blood pressure*** or a sudden drop in blood pressure. Hypotension may occur when a person rises quickly from a sitting or reclining position, causing dizziness or fainting.[1]

Hypo warning signals - When the level of glucose in a person's blood falls too low the person often experiences 'warning signs', which occur as the body tries to raise the blood glucose level. These warning signs vary from person to person, but often include feeling shaky, sweating, tingling in the lips, going pale, heart pounding, confusion and irritability.[2]

Impaired fasting glucose (IFG) - a condition in which a ***blood glucose*** test, taken after an 8- to 12-hour fast, shows a level of glucose higher than normal but not high enough for a diagnosis of ***diabetes***. IFG, also called ***pre-diabetes***, is a level of 6.1 ***mmol/l*** to 7 ***mmol/l***. Most people with pre-diabetes are at increased risk for developing ***type 2 diabetes***.[1]

Impaired glucose tolerance (IGT) - a condition in which ***blood glucose levels*** are higher than normal but are not high enough for a diagnosis of diabetes.

Continued overleaf

IGT, also called ***pre-diabetes***, is a level of 7.8 ***mmol/l*** to 11.1 ***mmol/l*** 2 hours after the start of an ***oral glucose tolerance test***. Most people with pre-diabetes are at increased risk for developing ***type 2 diabetes***. Other names for IGT that are no longer used are "borderline", "subclinical,", "chemical," or "latent" diabetes.[1]

Impotence - the inability to get or maintain an erection for sexual activity. Also called erectile dysfunction.[1]

Insulin - a ***hormone*** that helps the body use ***glucose*** for energy. The ***beta cells*** of the ***pancreas*** make insulin. When the body cannot make enough insulin, insulin is taken by ***injection*** or through use of an ***insulin pump***.[1]

Insulin resistance - the body's inability to respond to and use the insulin it produces. Insulin resistance may be linked to ***obesity***, ***hypertension***, and high levels of ***fat*** in the blood.[1]

Islets - groups of cells located in the ***pancreas*** that make ***hormones*** that help the body break down and use food. For example, ***alpha cells*** make ***glucagon*** and ***beta cells*** make ***insulin***. Also called islets of Langerhans.[1]

Ketoacidosis - see ***diabetic ketoacidosis***.

Ketone - a chemical produced when there is a shortage of ***insulin*** in the blood and the body breaks down body ***fat*** for energy. High levels of ketones can lead to ***diabetic ketoacidosis*** and ***coma***. Sometimes referred to as ketone bodies.[1]

Ketonuria - a condition occurring when ***ketones*** are present in the ***urine***, a warning sign of ***diabetic ketoacidosis***.[1]

Ketosis - ***ketone*** build-up in the body that may lead to ***diabetic ketoacidosis***. Signs of ketosis are nausea, vomiting, and stomach pain.[1]

Kidney disease - see ***nephropathy***.

Kidney failure - a ***chronic*** condition in which the body retains fluid and harmful wastes build up because the ***kidneys*** no longer work properly. A person with kidney failure needs ***dialysis*** or a kidney transplant. Also called end-stage renal disease or ESRD.[1]

Kidneys - the two bean-shaped organs that filter wastes from the blood and form ***urine***. The kidneys are located near the middle of the back. They send urine to the bladder.[1]

Continued overleaf

Glossary of terms

Lipids - a term for ***fat*** in the body. Lipids can be broken down by the body and used for energy.[1]

Lipid profile - a blood test that measures total ***cholesterol***, ***triglycerides***, and ***HDL cholesterol***. ***LDL cholesterol*** is then calculated from the results. A lipid profile is one measure of a person's risk of ***cardiovascular disease***.[1]

Liver - an organ in the body that changes food into energy, removes alcohol and poisons from the blood, and makes bile, a substance that breaks down ***fats*** and helps rid the body of wastes.[1]

Macrovascular disease - disease of the large ***blood vessels***, such as those found in the heart. ***Lipids*** and blood clots build up in the large blood vessels and can cause ***atherosclerosis***, ***coronary heart disease***, ***stroke***, and ***peripheral vascular disease***.[1]

Meglitinide - a class of oral medicine for ***type 2 diabetes*** that lowers ***blood glucose*** by helping the ***pancreas*** make more ***insulin*** right after meals. (Generic name: repaglinide.)[1]

Metabolic syndrome - the tendency of several conditions to occur together, including ***obesity***, ***insulin resistance***, diabetes or ***pre-diabetes***, ***hypertension***, and high ***lipids***.[1]

Metabolism - the term for the way cells chemically change food so that it can be used to store or use energy and make the ***proteins***, ***fats***, and ***sugars*** needed by the body.[1]

Metformin - an oral medicine used to treat ***type 2 diabetes***. It lowers ***blood glucose*** by reducing the amount of ***glucose*** produced by the ***liver*** and helping the body respond better to the ***insulin*** made in the ***pancreas***. Belongs to the class of medicines called biguanides. (Brand names: Glucophage, Glucophage XR; an ingredient in Glucovance.)[1]

Microalbumin - small amounts of the ***protein*** called albumin in the ***urine*** detectable with a special lab test.[1]

Microvascular disease - disease of the smallest ***blood vessels***, such as those found in the eyes, nerves, and ***kidneys***. The walls of the vessels become abnormally thick but weak. Then they bleed, leak ***protein***, and slow the flow of blood to the cells.[1]

Mitochondria - The powerhouses of the cell that convert glucose into energy.[2]

Continued overleaf

Glossary of terms

mmol/l - millimoles per litre, a unit of measure that shows the concentration of a substance in a specific amount of fluid.[1]

Mononeuropathy - ***neuropathy*** affecting a single nerve.[1]

Myocardial infarction - a sudden interruption in the blood supply to the heart because of narrowed or blocked ***blood vessels***. Also called a heart attack.[1]

Nephropathy - disease of the ***kidneys***. ***Hyperglycaemia*** and ***hypertension*** can damage the kidneys' ***glomeruli***. When the kidneys are damaged, ***protein*** leaks out of the kidneys into the urine. Damaged kidneys can no longer remove waste and extra fluids from the bloodstream.[1]

Neuropathy - disease of the nervous system. The three major forms in people with diabetes are ***peripheral neuropathy***, ***autonomic neuropathy***, and ***mononeuropathy***. The most common form is peripheral neuropathy, which affects mainly the legs and feet.[1]

Obesity - a condition in which a greater than normal amount of fat is in the body; more severe than ***overweight***, having a ***body mass index*** of 30 or more.[1]

Ophthalmologist - a medical doctor who diagnoses and treats all eye diseases and eye disorders. Opthalmologists can also prescribe glasses and contact lenses.[1]

Optometrist - a primary eye care provider who prescribes glasses and contact lenses. Optometrists can diagnose and treat certain eye conditions and diseases.[1]

Oral glucose tolerance test (OGTT) - a test to diagnose ***pre-diabetes*** and diabetes. The OGTT is given by a health care professional after an overnight fast. A blood sample is taken, then the patient drinks a high-***glucose*** beverage. Blood samples are taken at intervals for 2 to 3 hours. Test results are compared with a standard and show how the body uses glucose over time.[1]

Oral hypoglycaemic agents - medicines taken by mouth by people with ***type 2 diabetes*** to keep ***blood glucose levels*** as close to normal as possible. Classes of oral hypoglycaemic agents are ***alpha-glucosidase inhibitors***, ***biguanides***, ***D-phenylalanine derivatives***, ***meglitinides***, ***sulfonylureas***, and ***thiazolidinediones***.[1]

Overweight - an above-normal body weight; having a ***body mass index*** of 25 to 29.9.[1]

Pancreas - an organ that makes ***insulin*** and ***enzymes*** for digestion. The pancreas is located behind the lower part of the stomach and is about the size of a hand.[1]

Glossary of terms

Peripheral neuropathy - nerve damage that affects the feet, legs, or hands. Peripheral neuropathy causes pain, numbness, or a tingling feeling.[1]

Peripheral vascular disease (PVD) - a disease of the large ***blood vessels*** of the arms, legs, and feet. PVD may occur when major blood vessels in these areas are blocked and do not receive enough blood. The signs of PVD are aching pains and slow-healing foot sores.[1]

Plaque - a fatty deposit on the inner lining of an arterial wall, characteristic of atherosclerosis.

Polydipsia - excessive thirst; may be a sign of diabetes.[1]

Polyphagia - excessive hunger; may be a sign of diabetes.[1]

Polyuria - excessive urination; may be a sign of diabetes.[1]

Postprandial blood glucose - the ***blood glucose level*** taken 1 to 2 hours after eating.[1]

Pre-diabetes - a condition in which ***blood glucose levels*** are higher than normal but are not high enough for a diagnosis of diabetes. People with pre-diabetes are at increased risk for developing ***type 2 diabetes*** and for heart disease and ***stroke***. Other names for pre-diabetes are ***impaired glucose tolerance*** and ***impaired fasting glucose***.[1]

Protein - 1. One of the three main nutrients in food. Foods that provide protein include meat, poultry, fish, cheese, milk, dairy products, eggs, and dried beans. 2. Proteins are also used in the body for cell structure, ***hormones*** such as ***insulin***, and other functions.[1]

Proteinuria - the presence of ***protein*** in the ***urine***, indicating that the ***kidneys*** are not working properly.[1]

Renal - having to do with the ***kidneys***. A renal disease is a disease of the kidneys. Renal failure means the kidneys have stopped working.[1]

Retina - the light-sensitive layer of tissue that lines the back of the eye.[1]

Retinopathy - see ***diabetic retinopathy***.[1]

Risk factor - anything that raises the chances of a person developing a disease, e.g. age.[1]

Continued overleaf

Glossary of terms

Saturated fat - a type of fat that is generally solid at room temperature, and is found in animal products such as whole milk, eggs, and meats. Saturated fats are the biggest dietary cause of high LDL levels ("bad cholesterol").

Secondary diabetes mellitus - a type of diabetes caused by another disease or certain drugs or chemicals.[1]

Side effects - the unintended action(s) of a drug.[1]

Starch - another name for ***carbohydrate***, one of the three main nutrients in food.[1]

Statins - Any of a class of lipid-lowering drugs that reduce serum cholesterol levels by limiting the amount of cholesterol the body can make.

Stroke - condition caused by damage to ***blood vessels*** in the brain; may cause loss of ability to speak or to move parts of the body.[1]

Sugar - 1. A class of ***carbohydrates*** with a sweet taste; includes ***glucose***, ***fructose***, and ***sucrose***. 2. A term used to refer to ***blood glucose***.[1]

Sulphonylurea - a class of oral medicine for ***type 2 diabetes*** that lowers ***blood glucose*** by helping the ***pancreas*** make more ***insulin*** and by helping the body better use the insulin it makes. (Generic names: acetohexamide, chlorpropamide, glimepiride, glipizide, glyburide, tolazamide, tolbutamide.)[1]

Syndrome x - see ***insulin resistance*** and ***metabolic syndrome***.

Thiazolidinedione - a class of oral medicine for ***type 2 diabetes*** that helps ***insulin*** take ***glucose*** from the blood into the cells for energy by making cells more sensitive to insulin. (Generic names: pioglitazone and rosiglitazone.)[1]

Triglycerides - the storage form of ***fat*** in the body. High triglyceride levels may occur when diabetes is uncontrolled.[1]

Thyroid gland - a gland in the front of the neck that produces hormones to regulate the body's metabolism.

Type 1 diabetes mellitus - a condition characterized by high ***blood glucose levels*** caused by a total lack of ***insulin***. Occurs when the body's ***immune system*** attacks the insulin-producing ***beta cells*** in the ***pancreas*** and destroys them. The pancreas then produces little or no insulin. Type 1 diabetes develops most often in young people but can appear in adults.[1]

Glossary of terms

Type 2 diabetes mellitus - a condition characterized by high ***blood glucose levels*** caused by either a lack of ***insulin*** or the body's inability to use insulin efficiently. Type 2 diabetes develops most often in middle-aged and older adults but can appear in young people.[1]

Unsaturated fat - a type of fat that can help to lower blood cholesterol when used in place of saturated fats. There are two types: mono-unsaturated and polyunsaturated. Most liquid vegetable oils are unsaturated.

Urea - a waste product found in the blood that results from the normal breakdown of ***protein*** in the ***liver***. Urea is normally removed from the blood by the ***kidneys*** and then excreted in the ***urine***.[1]

Urine - the liquid waste product filtered from the blood by the ***kidneys***, stored in the bladder, and expelled from the body by the act of urinating.[1]

Urine testing - also called urinalysis; a test of a urine sample to diagnose diseases of the urinary system and other body systems. In people with diabetes, a doctor may check for:

1. ***Glucose***, a sign of diabetes or other diseases.
2. ***Protein***, a sign of kidney damage, or ***nephropathy***. (Also see albuminuria.)
3. ***White blood cells***, a sign of urinary tract infection.
4. ***Ketones***, a sign of ***diabetic ketoacidosis*** or other conditions.

Urine may also be checked for signs of bleeding. Some tests use a single urine sample. For others, 24-hour collection may be needed. And sometimes a sample is "cultured" to see exactly what type of bacteria grows.[1]

1. National Institutes of Health. Diabetes Dictionary. National Diabetes Clearing House (NDIC): A service of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), NIH. Website (www.diabetes.niddk.nih.gov/dm/pubs/dictionary/index.htm)

2. Diabetes UK. Glossary. Website (www.diabetes.org.uk/islets/gloss.htm)

PHYSICAL ACTIVITY

PHYSICAL ACTIVITY: CONTENTS

Continued overleaf

PHYSICAL ACTIVITY: CONTENTS

* Optional materials

EARLY ACTID

PHYSICAL ACTIVITY

Keeping track

PHYSICAL ACTIVITY: Keeping track

Pedometers: Instructions for use

- For accurate readings, your pedometer must be in an upright vertical position at all times, with the clip against your body. When you open the cover, the screen should face you.
- To prevent your pedometer falling off, attach the security strap's clip onto a belt loop, belt or waistband.

How do you open the pedometer?

- With your pedometer attached to your waistband or belt, grasp the top of the clip with one hand and use the other hand to push the cover away from the clip.

How do you reset the pedometer?

- To clear the data on your pedometer's screen, push the 'RESET' button.
- You should press 'RESET' each night, AFTER you have recorded your daily total steps and taken the pedometer off.
- You should press 'RESET' also at the start of the day, as soon as you have attached your pedometer. This will ensure you start the day with zero on the screen.

How do you check that your pedometer is recording accurately?

- Put the pedometer on, reset to '0' and close the cover.
- Walk forward 20 steps (right and left counts as two steps).
- Without removing the pedometer, carefully open the cover.
- If the pedometer does not read 19-21 steps and is not in a slanted position, move it to a different spot on the waistband, either further away or closer to the navel. Repeat the 20 steps until you find the most accurate position.

Recording your physical activity with a diary

Physical activity diary

Recording on the '*Physical activity diary*' the **STEP READINGS** from your pedometer and the **AMOUNT OF TIME** you spend being active each day will allow you to keep track of your physical activity.

Instructions for using the physical activity diary

You should record the following on the *front page* (PA.9) of the diary:

Time

- The TIME YOU PUT THE MONTIOR ON in the morning and the TIME YOU TAKE THE MONITOR OFF before bed.
- The TIME AT START and TIME AT END of each walking SESSION lasting at least 10 minutes.
- The DURATION of each walking SESSION, recorded in hrs:mins, which must be at least 10 minutes in duration to count toward your daily goal.
- The DAILY TOTAL TIME (hrs:mins) spent walking briskly.
- The WEEKLY TOTAL TIME spent walking briskly.

Steps

- The STEP READING AT START and END of each walking SESSION.
- The TOTAL STEPS walked in each SESSION.
- The DAILY TOTAL STEPS walked. This should be the last reading on your pedometer when you take it off before bed.
- WEEKLY TOTAL STEPS (calculated by adding the end of day readings).

Always remember to RESET your pedometer last thing at night, AFTER you have recorded your END OF DAY READING.

Continued overleaf

Recording your physical activity with a diary

You should record ACTIVITIES OTHER THAN WALKING on the *back page* (PA.10) of the physical activity diary, including:

- The TYPE OF ACTIVITY.
- The TIME AT START and TIME AT END of each activity SESSION lasting at least 10 minutes.
- The DURATION of activity SESSION, recorded in hrs:mins.
- The DAILY TOTAL TIME (hrs:mins) spent in other activities.
- The WEEKLY TOTAL TIME spent in other activities (calculated by adding the daily totals).

See the sample entry overleaf.

Weekly walking goal *an extra: 2hrs 30 mins/15000 steps* **Daily walking goal** *an extra: 30 mins/3000 steps x 5 days*

Day of week	Time (hrs:mins)				Steps			
Time Monitor on / *Time Monitor off*	Start of session	End of session	Duration of session	Daily total	Start of session	End of session	Total for session	End of day
Monday	1. *08.30*	*08:45*	*00:15*		*250*	*1500*	*1250*	
07:30	2. *17:00*	*17:15*	*00:15*	*00:30*	*3100*	*4610*	*1510*	*5010*
22:00	3.							
Tuesday	1. *08:35*	*08:50*	*00:15*		*200*	*1480*	*1280*	
07:40	2. *12:45*	*13:15*	*00:30*	*00:45*	*3490*	*6819*	*3329*	*9250*
22:30	3.							
Wednesday	1.							
07:45	2.			*00:00*				*2000*
22:15	3.							
Thursday	1. *12:40*	*13:10*	*00:30*		*1500*	*4500*	*3000*	
07:40	2.			*00:30*				*5100*
22:35	3.							
Friday	1. *12:50*	*13:00*	*00:10*		*2100*	*3000*	*900*	
07:45	2. *14:45*	*14:55*	*00:10*	*00:32*	*3458*	*4480*	*1022*	*6190*
00:00	3. *15:10*	*15;22*	*00:12*		*4610*	*5705*	*1095*	
Saturday	1. *11:00*	*11;20*	*00:20*		*1100*	*3010*	*1910*	
08:30	2. *12:05*	*12;28*	*00:23*	*00:43*	*4080*	*6280*	*2200*	*8225*
23:00	3.							
Sunday	1. *14:35*	*14:51*	*00:16*		*412*	*2100*	*1688*	
08:50	2.			*00:16*				*2950*
22:15	3.							
WEEKLY TOTALS			(mins:hrs)	*03:16*			(Steps)	*38725*

Continued overleaf

PHYSICAL ACTIVITY: Keeping track

Day of week	Activity description	Time (hrs:mins)				Notes
		Start of session	End of session	Duration of session	Daily total	
Monday	1.				00:00	
	2.					
	3.					
Tuesday	1.				00:00	
	2.					
	3.					
Wednesday	1. *Swimming*	10:20	10:50	00:30	00:30	
	2.					
	3.					
Thursday	1.				00:00	
	2.					
	3.					
Friday	1.				00:00	
	2.					
	3.					
Saturday	1.				00:00	
	2.					
	3.					
Sunday	1. *Badminton*		11:00	12:00	01:00	
	2.					
	3.					
				Weekly total (mins:hrs)	01:30	

Recording your physical activity on a graph

Physical activity graph

Monitoring the number of steps you walk day-by-day and month-by-month on a graph will enable you to easily see your progress over time. At a glance, you will see where you started and what you have been able to achieve. You may have episodes when you do not do as much activity, which will happen from time to time as you come across obstacles. This is normal and can help you prepare to overcome future barriers. What is important is that, overall, the trend is moving in the right direction.

Instructions for using the physical activity graph

- Your '***Physical activity graph***' is in the '***Progress Reports***' section of your file.
- Plot the total number of steps walked each day. This will be the reading recorded in the last column on PA.9 of your diary.
- Find the day of the month along the bottom of the graph and then find the number of steps up the left hand side of the graph. Mark where these two meet.
- Join the points plotted each day with a line.
- See the sample entry overleaf.

Continued overleaf

V5+DE

Physical activity diary: W/C ____

Wk # ____

Weekly walking goal _____ Daily walking goal _____

Day of week	Time (hrs:mins)				Steps			
Time monitor on / *Time monitor off*	Start of session	End of session	Duration of session	Daily total	Start of session	End of session	Total for session	End of day
Monday	1.							
Time monitor on	2.							
Time monitor off	3.							
Tuesday	1.							
Time monitor on	2.							
Time monitor off	3.							
Wednesday	1.							
Time monitor on	2.							
Time monitor off	3.							
Thursday	1.							
Time monitor on	2.							
Time monitor off	3.							
Friday	1.							
Time monitor on	2.							
Time monitor off	3.							
Saturday	1.							
Time monitor on	2.							
Time monitor off	3.							
Sunday	1.							
Time monitor on	2.							
Time monitor off	3.							
WEEKLY TOTALS	(mins:hrs)				(Steps)			

Continued overleaf

EARLY ACTID

PHYSICAL ACTIVITY: Diary

Day of week	Activity description	Time (hrs:mins)				Notes
		Start of session	End of session	Duration of session	Daily total	
Monday	1.					
	2.					
	3.					
Tuesday	1.					
	2.					
	3.					
Wednesday	1.					
	2.					
	3.					
Thursday	1.					
	2.					
	3.					
Friday	1.					
	2.					
	3.					
Saturday	1.					
	2.					
	3.					
Sunday	1.					
	2.					
	3.					
				Weekly total (mins:hrs)		

EARLY ACTID

PHYSICAL ACTIVITY

Goals and plans

PHYSICAL ACTIVITY: Goals and plans

Setting physical activity goals

Why type of physical activity should you do?

Brisk walking has been chosen for this intervention study because it is an affordable, enjoyable and easy exercise that almost everyone can do. No matter what your age, fitness level or lifestyle, you can benefit from brisk walking. And all you need to do it is a comfortable pair of shoes.

What is brisk walking?

- Brisk walking/physical activity should make you feel warm and slightly breathless.
- Your heartbeat will become a little faster, but should not race. We also call this moderate-intensity physical activity.
- You should feel some exertion but should be able to carry on a conversation comfortably during the activity.

How much?

- Your long-term goal is to do at least 30 minutes of brisk walking on 5 or more days a week, **OVER AND ABOVE** any activity that you were doing when you entered the study. This amounts to an extra 2.5hrs each week
- **YOU DO NOT HAVE TO DO THE EXTRA 30 MINUTES ALL IN ONE GO**. Doing 3 bouts of 10 minutes will have the same benefits.
- Activities that last less than 10 minutes will **NOT** count towards your long-term daily goal of 30 minutes. However, doing any activity in addition to your 30 minutes is likely to provide further benefit.

Continued overleaf

Setting physical activity goals continued

Starting gradually

Start off gradually, even if it is just walking for 5 minutes on a few days in the first week. It is important that you give yourself time to adjust, so it may take several weeks to build up to doing 30 minutes on 5 days a week.

Below is a chart suggesting how you can do this.

Week #	Total amount of physical activity	Examples
4	Do something active on 3 to 4 days	Walk to the local shops
5	60 minutes over 4 to 6 days	10 minutes per day on 6 days
6	90 minutes over at least 5 days	15 minutes per day on 6 days
7	120 minutes over at least 5 days	20 minutes per day on 6 days
8	150 minutes over at least 5 days	30 minutes per day on 5 days
9 & onwards	At least 150 minutes over 5 days or more	30 minutes or more per day on 5 days

Remember that 10 minutes of continuous brisk walking is approximately equal to 1000 steps.

Other brisk activities

Here are some other brisk activities that will provide extra benefit when done in addition to your walking.

Home

- ❑ Vacuuming
- ❑ Going up the stairs
- ❑ Cleaning windows
- ❑ Carrying small children
- ❑ Raking leaves
- ❑ Gardening
- ❑ Washing the car
- ❑ Decorating
- ❑ Exercise videos
- ❑ Other_____

Work

- ❑ Stair climbing
- ❑ Building work
- ❑ Other_____

Leisure

- ❑ Cycling <10mph on flat ground
- ❑ Continuous dancing (Line or ball room)
- ❑ Low-impact aerobics
- ❑ Water aerobics
- ❑ Walking in water (Widths across shallow end)
- ❑ Swimming
- ❑ Golf (without buggy)
- ❑ Rowing
- ❑ Racquet games (badminton, tennis, table tennis)
- ❑ Canoeing
- ❑ Roller-skating/ice-skating
- ❑ Team sports (football, netball, cricket)
- ❑ Other_____

Physical activity goals

EARLY ACTID

Visit..... Week..... Date:.....

My agreed goals are:

1._____

_____

_____

Motivation _____ Confidence _____

2._____

_____

_____

Motivation _____ Confidence _____

3._____

_____

_____

Motivation _____ Confidence _____

Signed.....Participant

Signed.....Nurse

Successes and difficulties

Visit _____

What are the successes since the previous visit? Remember that a success can be wearing a pedometer everyday during waking hours, keeping a physical activity diary every day, any increase in physical activity, or reaching a physical activity goal.

Were there any difficulties?

How can these be avoided in the future?

Physical activity plan

EARLY ACTID

W/C _____ Week # _____

Weekly goal: _____ Daily goal _____

Day	Activity	When	Where	Duration (hrs:mins)
Monday				
Tuesday				
Wednesday				
Thursday				
Friday				
Saturday				
Sunday				
			Total time for the week (hrs:mins)	

PHYSICAL ACTIVITY: Goals and plans

Continued overleaf

Physical activity plan

W/C _____ Week # _____

Weekly goal: _____ Daily goal _____

Day	Activity	When	Where	Duration (hrs:mins)
Monday				
Tuesday				
Wednesday				
Thursday				
Friday				
Saturday				
Sunday				
		Total time for the week (hrs:mins)		

EARLY ACTID

PHYSICAL ACTIVITY

Information sheets

PHYSICAL ACTIVITY: Information sheets

Troubleshooting your pedometer

The clip has broken

Contact your Early ACTID nurse for a replacement clip.

The pins that hold the clip on the pedometer have come out

Reinsert the pins or if you have lost them, contact the Early ACTID office.

The display is dim, flashing or showing dashes

Check to make sure the battery is making proper contact. If it is still not working properly, contact the Early ACTID office for a new battery.

The display is blank

If you have tried changing the battery, the display may be broken. Contact the Early ACTID office for a replacement pedometer.

The display is stuck on one number

Hold down the RESET button for five seconds. When the display goes blank, remove your finger from the button. Your display should now show '88888' and then '0'. If not, remove the battery. Put the battery back in. Your display should read '0'.

Continued overleaf

Troubleshooting your pedometer continued

The pedometer is wet or has been through the washing machine

Remove the battery immediately. Allow the pedometer to dry out naturally (do not use a dryer or radiator) for at least 24 hours. Put a new battery in (These can be obtained from the Early ACTID office).

The pedometer is not recording steps accurately

In most cases, problems with pedometers accurately recording steps can be resolved by adjusting the pedometer's position on your body. To record accurately, it is essential that the pedometer remains upright, and not tilted . If your stomach protrudes, try positioning the pedometer on the side of your hip, where it should remain vertical. To test the pedometer's accuracy in a new position, follow the step test instructions on PA.2. Repeat the test until you find the most accurate position. If it is still recording inaccurately, contact your Early ACTID nurse for a replacement pedometer.

The pedometer will not stay in an upright position

Contact your Early ACTID nurse for an elastic belt that you can clip your pedometer on to.

How do I wear a pedometer if I'm wearing a dress?

The pedometer and security strap can be attached to the waistband of your underwear. Alternatively, obtain an elastic belt from your Early ACTID nurse.

For other problems, contact your Early ACTID nurse.

Facts about walking

Benefits of walking

- Burns calories
- Increases the metabolism, even when resting
- Strengthens core muscles (back and stomach)
- Tones legs
- Improves fitness
- Improves circulation
- Improves immune system
- Strengthens bones and prevents osteoporosis
- Improves blood lipids
- Improves glycaemic control
- Lowers blood pressure
- Reduces risk of heart disease, stroke, and some cancers
- Reduces stress and anxiety
- Increases energy
- Improves quality of sleep
- Improves mood
- Can be done almost anywhere and by almost everyone
- Requires no training or equipment
- Is one of the simplest and safest forms of exercise
- Is free

Continued overleaf

Facts about walking continued

If you are still not convinced that walking is real exercise, have a look at these quick facts:

1. Walking one mile in fifteen minutes burns about the same number of calories as running a mile in 8.30 minutes.
2. A brisk one-mile walk in 20 minutes burns around 100 calories - as much as swimming for 10 minutes, playing football for 12 minutes or doing aerobics for 16 minutes.
3. Walking two miles a day, three times a week, can reduce your weight by one pound every three weeks.
4. Every minute you spend walking adds between one and a half to two minutes to your life - about a 2 for 1 trade off!
5. Exercising for ten minutes, three times a day is as beneficial as exercising continuously for 30 minutes once a day.

Staying safe: Foot care

Diabetes can sometimes affect the sensation in your feet and also the circulation to them. To prevent foot problems it is important that you:

- Check your feet daily for areas of redness, hard skin, blisters and breaks in the skin. You are looking for:
  - ⇒ Sores, cuts, bruises or injury;
  - ⇒ Any colour change, swelling, warmth or redness;
  - ⇒ Calluses or changes in the shape of your feet.
- Wash your feet regularly and dry carefully between the toes.
- Cut your toenails straight across (not down the sides), preferably after a bath when the nails are soft. Try not to cut your nails too short.
- Avoid walking barefoot.
- Always wear shoes that fit well; have your feet measured regularly.
- Always check inside your shoes for rough lining or loose objects before putting them on because there may be something inside your shoe that could hurt your foot.
- Be careful not to use anything hot on your feet.
- If your feet are dry and cracked, use moisturising cream recommended by your nurse.
- **If you notice any changes to your feet, or think you may have a foot problem, contact your Early ACTID nurse as soon as possible.**

Source: Avon diabetes 2006. Adapted from Footcare.
Website (www.avondiabetes.nhs.uk)

Continued overleaf

Staying safe: Foot care continued

Choosing the right footwear is an important part of foot care and is particularly important for those who are active.

What is a good shoe?

A good shoe is one that:

- Is deep enough at the front so that your toes are free to move.
- Has a thick bouncy flexible sole for cushioning.
- Has a low chunky heel or low wedge for balance.
- Holds the foot firmly in place by lace or strap for support.
- Is preferably made of leather (but not patent which is too hard).
- Has a smooth lining (stitching may rub).

How do I buy a good shoe?

- Be sure your feet are properly measured and fitted whenever you get new shoes as your feet can change size and shape. Shoes should fit both the length and width of your foot.
- Ask for your feet to be measured whilst standing.
- Try shoes on at the end of the day to allow for swelling.
- Walk around the shop in the shoes: new shoes should feel comfortable straight away.
- Try shoes on in your normal socks or tights.
- If a podiatrist has given you an insole or orthotic, take them with you when trying on a new pair of shoes.
- Go to a shop that has shoes in a wide range of sizes, including half sizes and different width fittings.

Source: Avon diabetes 2006. Adapted from Ideal footware.
Website (www.avondiabetes.nhs.uk)

Staying safe: Prevention

Being moderately active is usually very safe. In rare cases, however, problems can occur. We strongly recommend that you follow the advice below to prevent any problems.

- Start an activity programme slowly and build up gradually over a number of weeks. You increase your risk of injury if you try too much too soon. Increase the workload week by week to give your body time to adjust.
- Always tell someone where you are going and how long you are going to be there.
- Drink plenty of water before, during and after any activity.
- Always change your socks and wear appropriate and comfortable footwear. Check your feet daily and after activity for cuts and sores. If concerned, arrange to see a podiatrist.
- Always warm-up and cool down. Spend a few minutes before and after each session doing your activity but at a slower pace.
- At the end of each session, spend a few minutes stretching your muscles. This will prevent soreness and injury, and improve flexibility.

Continued overleaf

Staying safe: Illness

- Rest if you feel unwell and follow the steps below:

If you have unexplained chest pain/tightness, extreme shortness of breath, numbness or pins and needles while you are active, **STOP and SEEK URGENT MEDICAL HELP or DIAL 999.**

If you are suffering from a chesty cough, a bad cold, nausea, vomiting, flu or a temperature, **do not exercise until the symptoms have gone for 24 hours**. Restart gently and ease off if the symptoms start again.

If in doubt, wait it out. One day off will not hurt your fitness but exercising when ill can set you back a week or longer.

Remember:

Activity is good for you, but more activity is not necessarily better for you without a gradual build up. View your daily activity as the most normal thing in the world - our bodies are made for movement.

Activity is healthy, fun, sociable, normal and doesn't have to be expensive. Start slowly, increase gradually, try new activities, and get fit for life.

Source: Diabetes UK 2004. Information: Physical activity and diabetes. Website (http://www.diabetes.org.uk/infocentre/inform/downloads/physicalactivity.doc)

Staying safe: Hypos

If you take Metformin or Glucobay alone (not treated with insulin), you are very unlikely to have a hypo. However, you may need food soon after you have been active.

If you take insulin or sulphonylurea tablets, your planned activity should take into account the following:

- Injection sites should be away from areas used during your chosen activity.
- Fast-acting carbohydrate snacks should be to hand while being active, e.g. glucose tablets, Lucozade.
- Monitor blood glucose levels before and after activity and take necessary steps to prevent hypoglycaemia.
- Take monitoring equipment if your activity will last for an hour or more.
- Depending on the results of your pre-activity blood glucose test, you may well need to eat some starchy carbohydrate food before you start. However, if the test shows that your blood glucose level is 13mmol/l or above, you must also test for ketones (test strips are available from your Early ACTID nurse). Even if ketones are not present, there may still not be enough insulin for your muscles to be able to mobilise the energy needed to exercise. Your blood glucose level will rise further as a response to the activity and yet, without insulin, still not provide the muscles with energy. Delay the training session until your insulin has taken effect and your blood glucose level has come down.

Continued overleaf

Staying safe: Hypos continued

- If ketones are present, this indicates that fat is being metabolised for energy. If a positive ketone test accompanies a high blood glucose level, this may be a sign of ketoacidosis and you should seek medical help immediately.
- Delayed hypos (up to 36 hours) can occur as the muscles refuel after activity. Meal adjustments and bedtime snacks are advisable after intense activity.

Source: Diabetes UK 2004. Information: Physical activity and diabetes. Website (http://www.diabetes.org.uk/infocentre/inform/downloads/physicalactivity.doc)

Staying safe: Stretching

The aims of stretching are to gently lengthen muscles after any form of exercise, and to improve tissue elasticity and flexibility. If done correctly, stretching will help:

- Prevent soreness
- Prevent injuries
- Maintain full range of movement
- Improve flexibility

Stretching should always be done **after any activity**, once you have decreased your intensity, but are still warm. Move gently into the stretch position and hold (taking care NOT to bounce) the stretch for at least ten seconds, preferably between 15 and 30 seconds, until you feel the stretch ease off.

You should feel a gentle pull in the muscles you are intending to stretch - not a searing pain. Stop immediately if you do feel any severe pain. Either adjust your position, or try a different stretch instead. It is advisable to use support, such as walls or chairs, to prevent overbalancing or strain. Breathe slowly and naturally. Try NOT to hold your breath.

Continued overleaf

Staying safe: Stretching continued

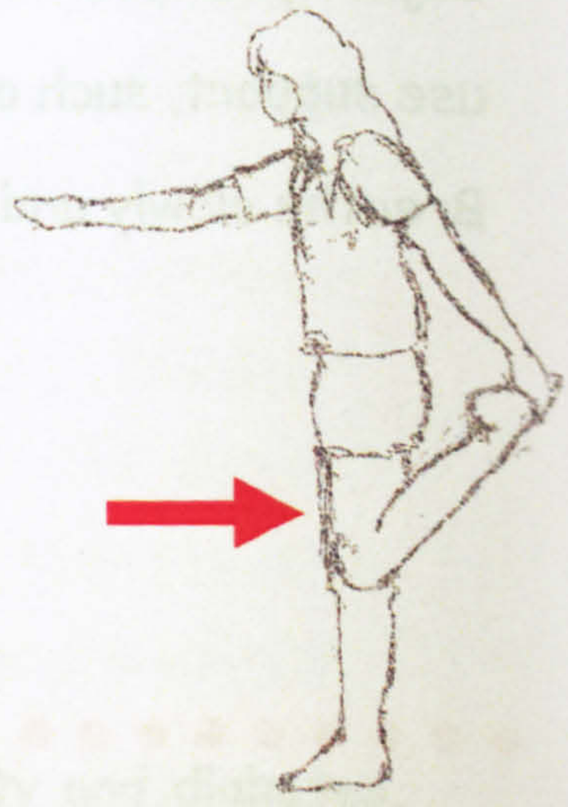
Here are some safe stretches that your nurse can demonstrate.

Calf stretch

- Stand 2 to 3 ft. from a wall. Lean forward supporting your body weight with your bent arms.
- Straighten your right leg behind. Press your heel to the floor.
- You should feel the stretch in your right calf.
- Hold the stretch for 15 to 30 seconds, whilst breathing steadily and then repeat on the other side.

Quadriceps (front of thigh) stretch

- Stand with your legs hip-width apart.
- Raise your left arm and hold on to something for balance.
- Bend your right knee backwards. Reach behind with your right hand and hold your ankle or foot.
- Avoid pulling your heel towards your buttocks. Instead, press your hip forward.
- You should feel the stretch in the front of your right thigh.
- Hold the stretch for 15 to 30 seconds, whilst breathing steadily and then repeat on other side.



Continued overleaf

Staying safe: Stretching continued

Waist, arm and shoulder stretch

- Stand with your feet apart and knees slightly bent.
- Hold your elbow with the hand of your opposite arm.
- Pull your elbow behind your head very gently.
- Slowly lean to the side until you feel a mild stretch.
- Hold the stretch for 15 to 30 seconds, whilst breathing steadily and then repeat on the other side.

Hamstring (back of thigh) stretch

- Stand with your right leg in front of you with your foot flexed. The weight of your body will be carried by your left leg.
- Keeping your hips square (facing forward), bend your left knee and slowly push your buttocks out.
- Keep your right leg straight and place your hands (to support your back) on the thigh of your left leg.
- Keep your back straight by keeping your abdominal muscles tight and your chest opened up.
- You should feel the stretch in the back of your right leg.
- Hold the stretch for 15-30 seconds., while breathing steadily and then repeat on the other side.

EARLY ACTID

PHYSICAL ACTIVITY

Gaining confidence

Gaining confidence – PHYSICAL ACTIVITY: @

Physical activity history

EARLY ACTID

Current physical activity (Typical week-Type of activity, how often/long)

Past physical activity (Type of activity, when, how often/long)

What helped you succeed?

What got in the way?

Continued overleaf

Physical activity history continued

Why did you stop?

_____

_____

_____

Benefits of physical activity

Being active is good for all of us but is especially important if you have diabetes. Here are some of the benefits that people get from physical activity.

Physical health

- Reduced risk of heart disease
- Reduced risk of some cancers
- Lower blood pressure
- Lower 'bad' cholesterol
- Improved blood glucose levels
- Improved insulin sensitivity
- Improved circulation
- Improved lung capacity
- Less chance of colds and flu
- Better weight control
- Improved appetite control
- Reduced fat around the organs
- Improved flexibility
- Healthy and strong bones, joints and muscles

Well-being

- More energy
- Improved mood
- Increased self-esteem
- Improved quality of sleep
- Reduced stress
- Feeling productive
- A sense of achievement
- Feeling good about your body

Social

- Able to play with children without being tired
- Encourages social interaction
- Living a healthier and longer independent life

PHYSICAL ACTIVITY: Gaining confidence

Continued overleaf

Pros and cons of physical activity

You may have thought about other benefits of physical activity that are especially important to you. There may also be things that you feel are NOT so good about physical activity. **Take a few moments now to list the pros and cons of physical activity that you consider most important, and that matter to you personally. You can add to this list throughout the study.**

Pros	Cons

Now try to think about whether there are strategies you can use to minimise the things that are not so good . Record any ideas in the space below.

Lifestyle activity

In addition to the activity that contributes to your weekly goal, it is recommended that you try to make active choices throughout the day. For example, you could choose to take the stairs instead of the lift or escalator.

Using the table overleaf, take a few moments to list some active choices that you can substitute for current inactive choices. It is important that your active choices work for you and can fit into your lifestyle.

Here is a sample entry

Inactive choice	Active choice
1. Using the lift at work	1. Taking the stairs
2. Driving to the local shops	2. Walking to the local shops
3. Getting the bus all the way to work	3. Getting off the bus a stop earlier

 Continued overleaf

Lifestyle activity continued

You may find it useful to see "*Opportunities to be active*" for some ideas.

Inactive choice	Active choice

You can add to this list throughout the study.

Opportunities to be active

At home

- ❑ Try to do something active during television adverts.
- ❑ Get up and manually change the television channel instead of using the remote control.
- ❑ Walk while you talk on a cordless phone, or do 'step-ups' at the bottom of the stairs.
- ❑ Go up and down the stairs whenever the opportunity arises.
- ❑ Do housework to music, it's fun and the chores seem easier.
- ❑ Wash your car by hand instead of taking it to the car wash.
- ❑ Do some gardening.
- ❑ Clean the windows.
- ❑ _____
- ❑ _____

At work

- ❑ Use the stairs instead of the lift or escalator.
- ❑ Take the long way to the bathroom, using the stairs if possible.
- ❑ Walk to visit colleagues instead of calling or e-mailing them.
- ❑ Plan active meetings and walk while you talk.
- ❑ Take a 10-minute walk at lunchtime or during your break at work.
- ❑ _____
- ❑ _____

Continued overleaf

Opportunities to be active continued

Leisure time

- ❑ Park the car further away from your destination.
- ❑ Actively play with children rather than sitting and watching, e.g. go to the park; play with a ball.
- ❑ Plan active occasions with your family, e.g. bike rides, swimming.
- ❑ Plan active social events, e.g. go dancing or bowling instead of going to dinner or the cinema.
- ❑ Walk with a partner or in groups of friends, e.g. arrange to walk a friend's dog.
- ❑ Join your local leisure centre.
- ❑ Take up an active hobby, such as line dancing, salsa, netball, football.
- ❑ _____
- ❑ _____

Travelling

- ❑ Use public transport – you will walk more than if you drive.
- ❑ Get off the bus one or more stops earlier and walk the last distance.
- ❑ Walk or cycle to nearby shops or restaurants instead of driving.
- ❑ Park the car further away from your work place.
- ❑ Walk around the airport instead of using the moving travelator.
- ❑ Walk children to and from school instead of using the car.
- ❑ _____
- ❑ _____

Preventing relapses

Making lifestyle changes are the first big steps to leading a healthier life and controlling your diabetes. Maintaining these changes as a permanent lifestyle is a huge achievement and requires a lot of commitment. Unfortunately, there can be many hurdles that get in the way of you maintaining changes, and there will be times when you don't follow your plans for being active. These are called LAPSES and are a normal part of change.

Occasional lapses from time to time will not harm your progress. However, when these start to occur regularly, you might experience a RELAPSE — a permanent return to old habits. Taking time to think about what causes you to lapse, and how best to prevent, or react to lapses will reduce your risk of relapsing into lower physical activity levels.

What causes you to lapse?

Take a few moments to think about specific things that might cause you to lapse during your physical activity programme. These might include being busy at work or feeling tired, etc. In the table overleaf, write your personal triggers in the left hand column. Once you have listed these, brainstorm ideas to overcome them. Here is a sample entry.

Triggers or risky situations that can cause you to lapse	What can you do to prevent these lapses
1. Busy at work	1. Plan time for physical activity or Walk to and from work

Continued overleaf

Preventing relapses continued

You might find it useful to see '***Overcoming barriers to physical activity***'.

Triggers or risky situations that can cause you to lapse	What can you do to prevent these lapses

How to recover after a lapse

- **Stay calm and don't panic**. One lapse does not mean you have failed, or that you have to wait to the next day or week to get back on track. Try to resume your day as if you had not had the lapse.
- **Replace negative thoughts with positive thoughts**. Rather than feeling discouraged, guilty and angry, remind yourself of how much you have achieved so far.
- **Learn and plan ahead**. Try to think about how you can use the lapse as a learning experience. What were the triggers? How can you plan ahead and prevent future lapses?

Barriers to physical activity*

We all have barriers that stop us from being more physically active. **Take a few moments to think about what your own personal barriers are that prevent you from being more active.**

1. _____

2. _____

3. _____

4. _____

5. _____

6. _____

Most barriers can be easily overcome. For ideas, you may like to see '***Overcoming barriers to physical activity***'. **Take a few moments to brainstorm strategies to overcome your personal barriers.**

1. _____

2. _____

3. _____

4. _____

5. _____

6. _____

Continued overleaf

Overcoming barriers to physical activity continued

BARRIER	HOW TO OVERCOME IT
Circumstantial	
Lack of time	• Keep a time diary for a couple of days and identify available 10-minute time slots that can be used for physical activity. Complete a '***Personal time diary***'. • Add physical activity to your daily routine. For example, walk or ride a bike to work or the local shops; walk children to school, walk the dog, exercise while you watch TV, park further away from your destination, etc. See '***Opportunities to be active***'. • Make time for physical activity. For example, walk, jog, or swim during your lunch hour, or take activity breaks instead of coffee breaks.
Lack of resources (financial, access to facilities, no safe place to exercise)	• Choose activities that require minimal facilities or equipment, such as walking, stair-climbing, dancing, etc. • Find out about inexpensive, convenient resources available in your local area (worksite programs, group walks, etc.). Use the worksheet '***Local exercise opportunities***' to record what's available in your area. • For safety, there are activities that you can do at home, in groups, or at supervised facilities.
Weather conditions	• Develop a set of regular activities that are always available regardless of weather (stair climbing, dancing, exercising with a home video, indoor swimming, using indoor exercise equipment, indoor games, indoor walking, local exercise classes, etc.).
Holiday	• Look for opportunities to be active. Explore an area by walking. Make the most of swimming pools and access to other activity or exercise facilities.

Continued overleaf

Overcoming barriers to physical activity continued

BARRIER	HOW TO OVERCOME IT
Circumstantial continued	
Family obligations	• Exercise with the children: go for a walk together, play energetic games, get an aerobic dance or exercise tape for children and exercise together. You can spend time together and still get your exercise. • Try to exercise when the children are not around (e.g., during school hours or their sleep time). • Use home equipment while the children are busy playing or sleeping. • Find a friend or family member to help with care, while you exercise. • Trade babysitting time with a friend, neighbour, or family member who also has small children. • Use exercise facilities that provide child care services. • Hire a babysitter and look at the cost as a worthwhile investment in your physical and mental health.
Retirement	• Look upon your retirement as an opportunity to become more active instead of less active. Spend more time gardening, walking the dog, and playing with your grandchildren. Children with short legs and grandparents with slower gaits are often great walking partners. • Learn a new skill you have always been interested in, such as ballroom dancing or swimming. • Now that you have the time, make regular physical activity a part of every day. Go for a walk every morning or every evening before dinner. Get yourself a stationary bike and ride every day while reading a favourite book or magazine.

Continued overleaf

Overcoming barriers to physical activity continued

BARRIER	HOW TO OVERCOME IT
Physical	
Aches and pains	• When you begin to exercise, you might experience some soreness in your muscles. This is normal. To reduce any discomfort, try stretching after each exercise session. • If you have joint pain, try activities that are non-weight bearing, such as swimming or cycling. • Being active will help build your muscles to protect your joints in the future.
Tiredness	• Schedule physical activity for times in the day when you feel more energetic. • Physical activity can increase your energy levels: try it!
Lack of skill	• Select activities requiring no new skills, such as walking, cycling, or stair climbing. • Exercise with friends who are at the same skill level as you are. • Find a friend who is willing to teach you some new skills. • Take a class to develop new skills.
Fear of injury	• Start gradually, and stretch before and after each exercise session. • Walking has minimal risk of injury.
Diabetes specific	
Foot problems	• Maintain a good foot care routine, checking your feet daily, and after any exercise session for cuts or anything unusual. Contact your chiropodist or Early ACTID nurse if any changes occur. • Wear good-fitting shoes, appropriate for exercise. • If you have foot problems, avoid weight-bearing exercise and opt for swimming, cycling or rowing activities instead. • See '***Foot care***' in your information section.

Continued overleaf

Overcoming barriers to physical activity continued

BARRIER	HOW TO OVERCOME IT
Diabetes specific continued	
Fear of hypo	• Unless you inject insulin or take sulphonylurea tablets, you are very unlikely to have a hypo. • If you are taking insulin or sulphonylurea tablets, always have some fast-acting carbohydrate to hand. See '***Staying safe: Hypos***'.
Psychological	
Lack of self-motivation	• Remember the benefits of being active. Look back at your '***Pros and cons of physical activity***'. • Plan ahead. Make physical activity a regular part of your daily or weekly schedule and write it in your diary. • Invite a friend to exercise with you on a regular basis and write it on both your diaries. • Join an exercise group or class. • Recognise the positive changes that you have made and consider all of your successes. Think back to how different things were at the start of the programme, and what you have gained as a result of your hard work. • Keep visible signs of your progress to see how far you have come. • Think about reward strategies for every goal you reach.
Exercise is boring or not enjoyable	• Try listening to music during your activity. It will help keep your mind occupied. • Walking or biking can take you past interesting scenery. • You don't have to "exercise". Start an active hobby that you do enjoy. • Find out what's on in your local area and record the information using '***Local exercise opportunities***'.
Too embarrassed	• Activity is for people of all ages and shapes. Exercise with people you feel comfortable, to build your confidence. • Try to exercise in places where you feel comfortable.

Continued overleaf

Overcoming barriers to physical activity continued

BARRIER	HOW TO OVERCOME IT
Social support	
No one to exercise with	• Invite friends and family members to exercise with you. Plan social activities involving exercise. • Find out about local group walks or clubs and develop new friendships with physically active people. • Record useful information using '***Local exercise opportunities***'.
Family and friends do not provide support	• Explain to friends and family how important physical activity is to the control of your diabetes and general health. Ask them to support and recognise your efforts. • Bring a family member or friend to your Early ACTID meeting. • Complete the worksheet '***People to help you achieve your goals***'.

Personal time diary*

One of the most common barriers to an active lifestyle is thinking that you don't have enough time to exercise. It can sometimes be difficult to find opportunities to be active, so here is a task that will help you understand how you spend your time. By doing so, you'll identify opportunities for activity you might not have considered before.

Select one typical weekday and one typical weekend day over the next week. Then, using the personal time diary worksheet, record how you spend each 2 hours during the 24-hour period. When recording your activities, calculate how many minutes you spend doing any type of physical activity, and how many minutes you spend being inactive. Go over your time diary and identify any opportunities to increase your activity. Any 10-minute slots will count towards your goal.

Here is a sample entry.

Time	Task	Minutes of activity	Minutes of inactivity	Opportunities for activity	Minutes
4:01 to 6:00pm	Desk work	0	90	Walk part of journey	30
	Walk to bus	4	0		
	Bus journey	0	21		
	Walk home	5	0		
6:01 to 8:00pm	Make/eat tea	0	30		
	Sort paperwork	0	90		
8:01 to 10:00pm	Phone calls	0	30	Walk with a cordless phone	30
	Watch TV	0	90		
	TOTAL	9	351	**TOTAL**	60

Continued overleaf

Personal time diary*

Date _____ Day of week _____

Time	Task	Minutes of activity	Minutes of inactivity	Opportunities for activity	Minutes
Midnight to 2:00am					
2:01 to 4:00am					
4:01 to 6:00am					
6:01 to 8:00am					
8:01 to 10:00am					
10:01 to Noon					
Noon to 2:00pm					
2:01 to 4:00pm					
4:01 to 6:00pm					
6:01 to 8:00pm					
8:01 to 10:00pm					
10:01 to Midnight					
	TOTAL			TOTAL	

PHYSICAL ACTIVITY: Gaining confidence

Continued overleaf

Personal time diary*

Date _____ Day of week _____

Time	Task	Minutes of activity	Minutes of inactivity	Opportunities for activity	Minutes
Midnight to 2:00am					
2:01 to 4:00am					
4:01 to 6:00am					
6:01 to 8:00am					
8:01 to 10:00am					
10:01 to Noon					
Noon to 2:00pm					
2:01 to 4:00pm					
4:01 to 6:00pm					
6:01 to 8:00pm					
8:01 to 10:00pm					
10:01 to Midnight					
	TOTAL			TOTAL	

People to help you achieve your goals*

The role of social support can be very important in helping you reach your physical activity goals. **Take a few moments to think of anyone who can help you stick with your physical activity programme. In the table overleaf, write down what they can do to help you. Sometimes, there might be things that you would like them NOT to do.**

For example, would you like someone to:

- ❑ Be active with you
- ❑ Listen to your successes and difficulties
- ❑ Encourage and motivate you to be active
- ❑ Offer expert advice (i.e. health professional, personal trainer, books, etc.)
- ❑ Make it easier for you to be active (i.e. help with housework or look after those you are responsible for so you have time to do something active, etc.)
- ❑ Other _____
- ❑ Other _____

Here is a sample entry.

Name	What things would you like them to do to help?	What things would you like them NOT to do?
Partner	1. Exercise with me, e.g. evening walks together. 2. Motivate me to exercise and support my efforts.	1. Encourage me to miss exercise sessions.

Continued overleaf

People to help you achieve your goals continued

Name	What things would you like them to do to help?	What things would you like them NOT to do?

You can add to this list throughout the study.

Local exercise opportunities*

Use this space to record any local exercise opportunities that might help you maintain an active lifestyle. For example, local group walks, group sports, opening times of exercise facilities. Your Early ACTID nurse can help you find out about these opportunities.

Continued overleaf

Local exercise opportunities continued

Use this space to record any local exercise opportunities.

PROGRESS REPORTS

PROGRESS REPORTS: CONTENTS

PAGE

Measurement	Months since randomisation												
	0	1	2	3	4	5	6	7	8	9	10	11	12
ANTHROPOMETRY													
Height (cm)													
Weight (kg)													
BMI (kg/m^2)													
Waist circumference (cm)													
Body fat (%)													
PHYSIOLOGICAL													
Blood pressure (mmHg)													
BLOOD LIPIDS (mmol/l)													
Total fat (cholesterol)													
Good fat (HDL cholesterol)													
Bad fat (LDL cholesterol)													
Other fat (triglycerides)													
GLYCAEMIC CONTROL OVER 6 MONTHS													
HbA1c (%)													
URINE													
Protein (microalbuminuria) Y or N													
Albumin:Creatinine Y or N													
Glucose Y or N													

PROGRESS REPORTS

Weight chart: Weeks 1-26

Week	Date	Time	Weight (kg)	Weight change (kg)
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				
12				
13				
14				
15				
16				
17				
18				
19				
20				
21				
22				
23				
24				
25				
26				

Continued overleaf

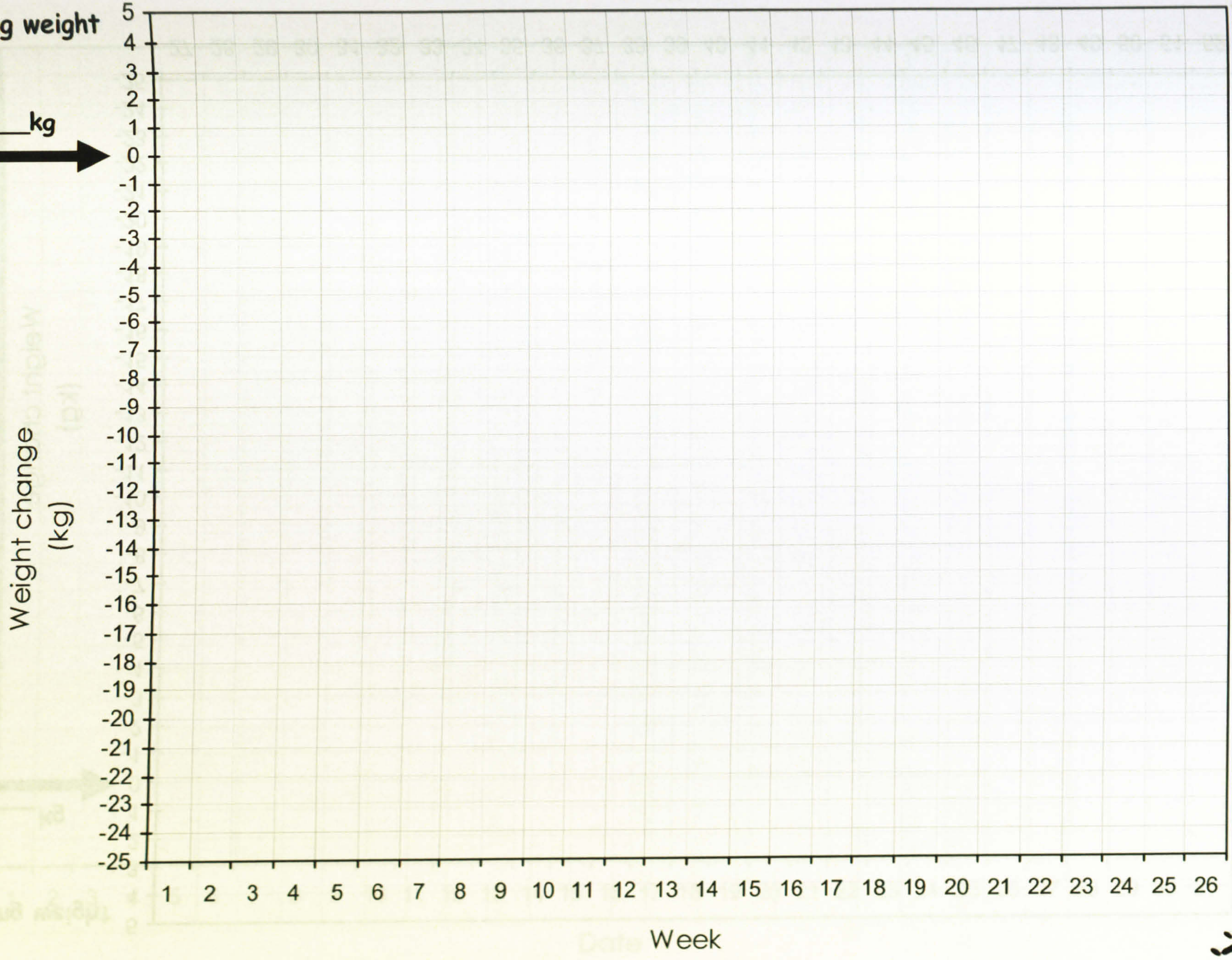
Weight chart: Weeks 27-52

Week	Date	Time	Weight (kg)	Weight change (kg)
27				
28				
29				
30				
31				
32				
33				
34				
35				
36				
37				
38				
39				
40				
41				
42				
43				
44				
45				
46				
47				
48				
49				
50				
51				
52				

Weight graph: Weeks 1-26

Your starting weight

_____kg



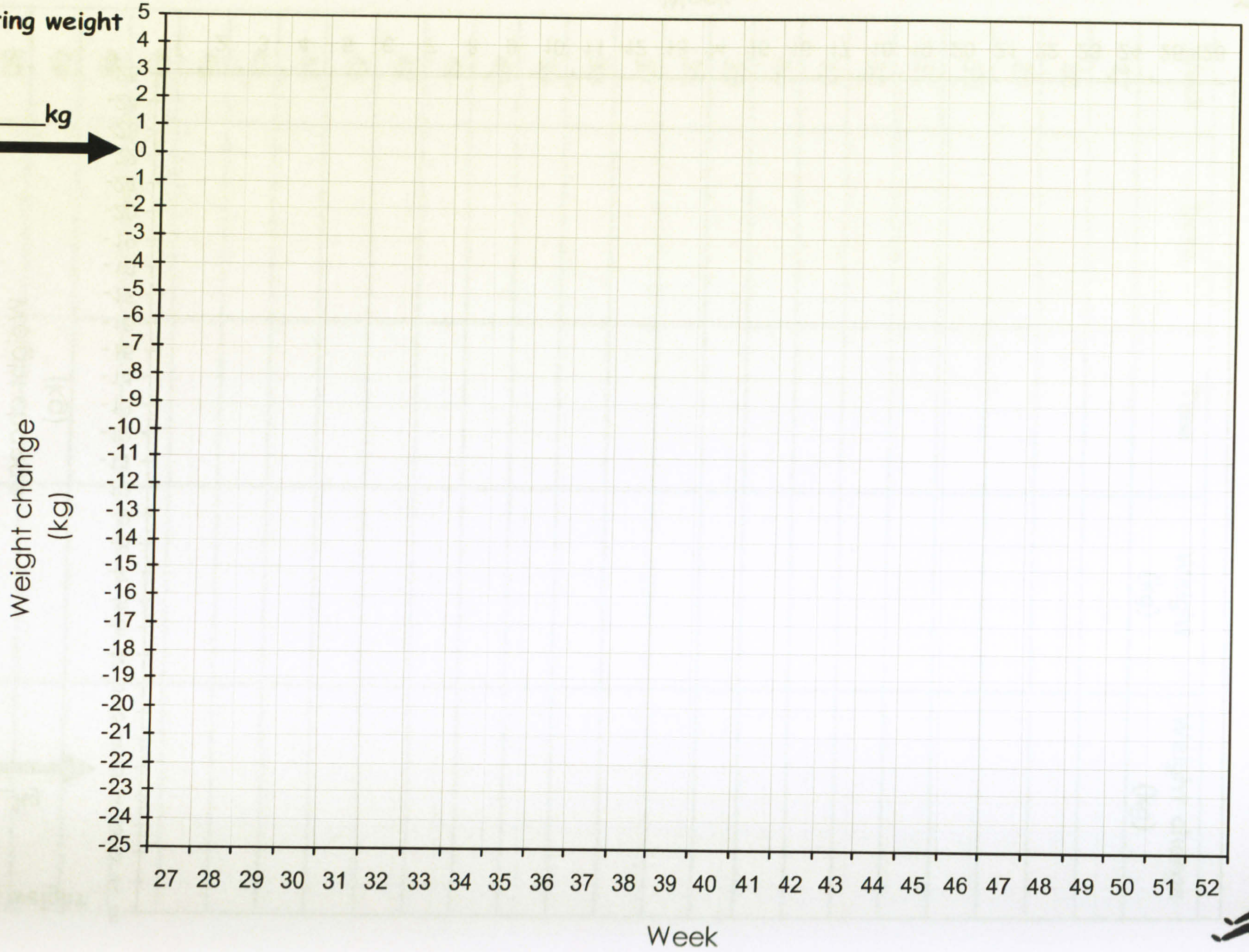
Continued overleaf

PROGRESS REPORTS

PROGRESS REPORTS

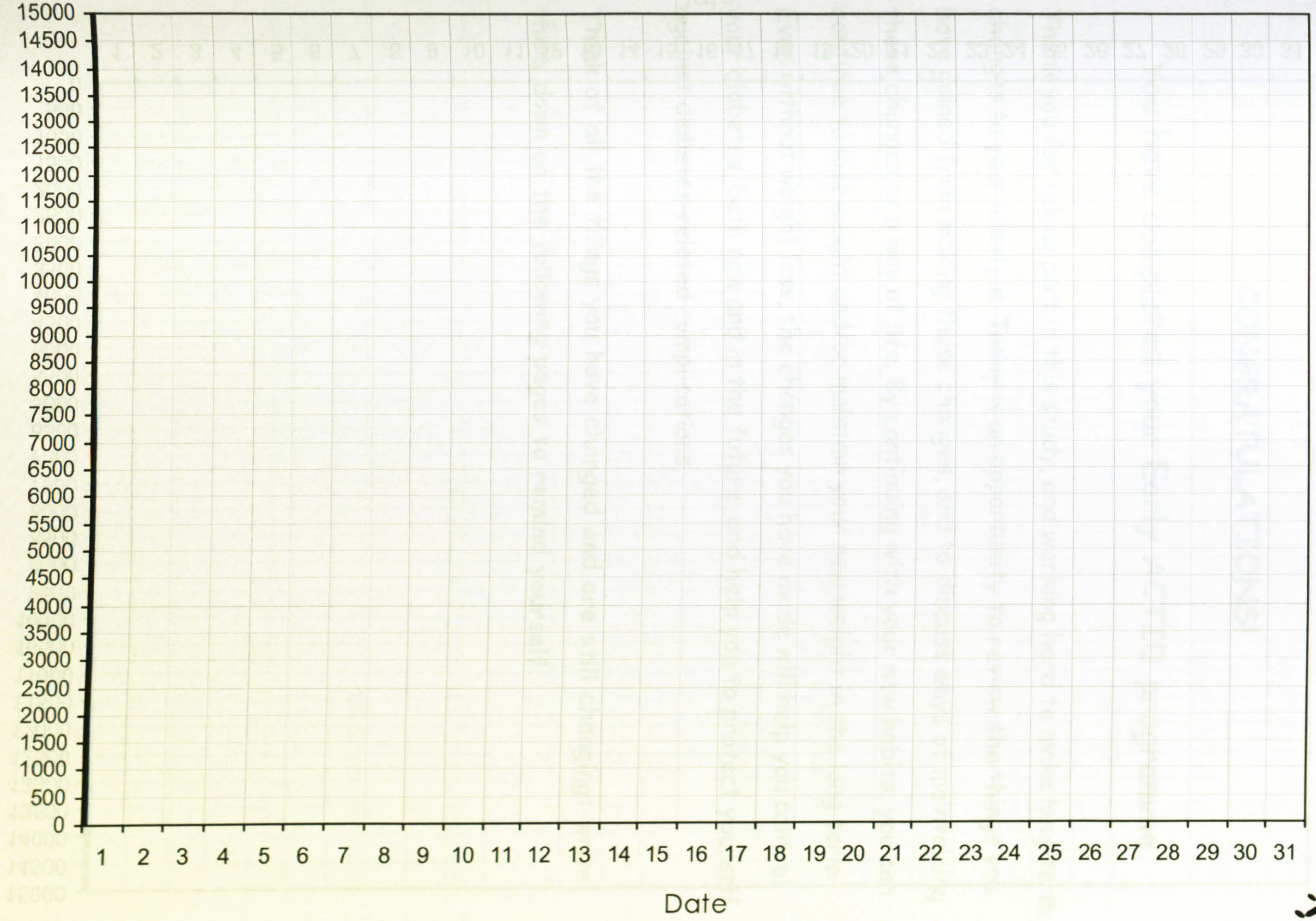
Your starting weight

_____kg



Weight graph: Weeks 27-52

Physical activity graph: Month ____



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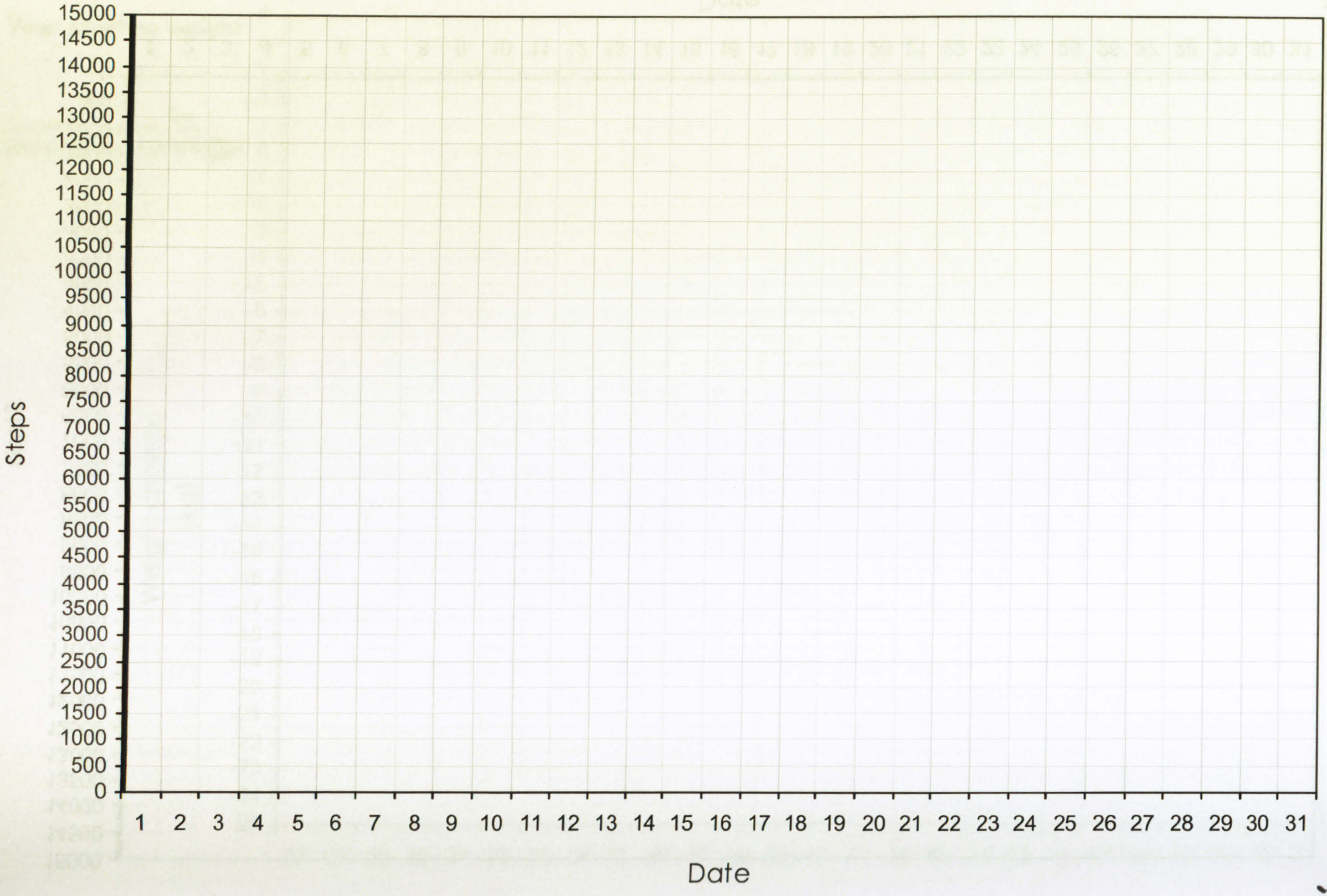
PROGRESS REPORTS



Physical activity graph: Month _____

EARLY ACTID

CONGRATULATIONS!

You have completed your Early ACTID programme.

Thank you for taking part in this study, and working hard to make long-term changes to your lifestyle. Today is an opportunity to review the things you have gained from making these changes, and to discuss ways of maintaining these changes as a way of life. By continuing with your new habits, you can continue to lose weight and/or maintain your new weight in the long term. Even without weight loss, the changes you have made will help you control your diabetes, both now and in the future, and help you to protect yourself against diabetes-related complications.

Think of all the things you have changed and are still changing: write them down on the following pages to remind yourself.

Continued overleaf

Reviewing your progress continued

The types of food

I have changed..._____

The amount of food

I have changed..._____

How often I eat

Now I..._____

Continued overleaf

Shopping

Now I..._____

Snacks

I have changed..._____

When I feel the urge to eat

Now I..._____

Continued overleaf

Reviewing your progress continued

The type of physical activity

Now I..._____

The amount of physical activity

Now I..._____

How often I am physically active

Now I..._____

Continued overleaf

Reviewing your progress continued

Now think about how all these positive changes to your eating habits and lifestyle have benefited you.

My weight is...

My waist measures...

I feel...

I am able to ...

Continued overleaf

Planning ahead

Without making and maintaining these changes to your diet and lifestyle, it will be very difficult to continue towards your weight goals, and/or keep your new healthier weight.

How to keep going

Some clues to long-term weight loss come from people who have successfully lost weight and kept it off. Several studies have looked at these kinds of people and carefully examined what they do and how they behave.

⇒ Dietary changes

Firstly, these people all chose a low-fat diet, with more high fibre starchy foods and plenty of fruit and vegetables. They all ate regular meals and planned snacks and ate smaller portion sizes. You can refer back to visits 4, 6, 9 and 10 to refresh yourself about these kinds of dietary changes.

⇒ Goal setting

These people also set themselves realistic goals, which we talked about at visit 4 and 5 and have mentioned throughout the programme.

⇒ Self monitoring

People who successfully managed their weight also regularly monitored their food intake, body weight, and daily physically activity.

Throughout the study, you have regularly completed food diaries. We would encourage you to record a food diary from time to time to check

Continued overleaf

that you are still on track with your dietary changes. You will be aware of the sorts of food and amounts of food that you need to be eating. Filling out a food diary at intervals will allow you to make a check on yourself and re-adjust if you need to.

If you were in the *Healthy eating plus physical activity group*, you will have been asked to record your daily physical activity with a diary. People who are regularly active, tend to monitor their physical activity (with a pedometer, and /or activity log), so they are able to track their progress and prevent relapse. We would encourage you to continue with this, so that you can be sure you're doing enough physical activity to look after your health, and help you manage your weight.

⇒ **Physical activity**

Numerous studies show that people who are regularly active are most successful at maintaining a healthier weight after weight loss, compared with people who rely on diet alone.

⇒ **Help and support**

Lastly, but still very important, people who were successful at reaching and maintaining a healthier weight sought help from people that would give them the support they needed. For example, friends, family, a self-help group (e.g. a slimming group) or a health professional.

We would encourage you to think about who you have turned to during this programme and continue to seek their support as you carry on with your healthy eating and physical activity.

Continued overleaf

Planning ahead continued

Use the space below to list the things that will help you to control your diabetes, maintain your new weight, or reach your goal weight.

What do you plan to continue doing?

What do you plan to do more of?

What do you plan o do less of?

What do you plan to start doing?

What do you plan to stop doing?

Continued overleaf

We hope you continue to benefit from your healthier lifestyle, and wish you every success in the future.

PERSONAL NOTES

PERSONAL NOTES: CONTENTS

PAGE

Personal notes

EARLY ACTID

You can use this space to record any notes, questions or queries.

PERSONAL NOTES

Continued overleaf

Personal notes continued

PERSONAL NOTES

Continued overleaf

Personal notes continued

Continued overleaf

Personal notes continued

Continued overleaf

Personal notes continued

EARLY ACTID

PERSONAL NOTES

Continued overleaf

Personal notes continued

Appendix 7. Information sheet: Reviewing draft materials for the Early ACTID Participant Record File

University of BRISTOL

Early ACTID Study
Joint Clinical Research Unit
Level 5 Old Building, near Ward 29
Bristol Royal Infirmary
Marlborough Street
BRISTOL BS2 8HW

Tel: +44 (0117) 9282440
Fax: +44 (0117) 9284470
E mail: Early-ACTID@bristol.ac.uk

Information about the Early ACTID study

The effects of diet and exercise in the management of Type 2 diabetes: A randomised controlled trial: The Early ACTID Study

What is the Early ACTID study?

Early ACTID stands for **Early ACT**ivity **I**n **D**iabetes. The study will investigate the effects of intensive dietary advice and increased exercise in the management of Type 2 diabetes, compared with usual care. Although we know a lot about how diet can control glucose levels and improve blood pressure and cholesterol, very little is known about how, or if exercise affects these factors. The Early ACTID study aims to answer these questions for the first time, and will be the largest diet and exercise trial in the world for people with type 2 diabetes.

Who are we?

The NHS and the charity Diabetes UK have funded the project, which has been designed by doctors and scientists from the University of Bristol who are specialists in diabetes and exercise. Early ACTID is being run from the Bristol Royal Infirmary and we are recruiting patients across the South-West region, with participants being seen at their local hospital.

What will the Early ACTID study involve?

The study aims to recruit 750 people from across the Southwest who have been newly diagnosed with type 2 diabetes within the last six to eight months. Individuals will be allocated to one of three groups:

1. **Control group:** People in this group will receive usual care.
2. **Diet group:** People in this group will receive regular help and advice on improving their diet
3. **Diet plus Exercise group:** People in this group will receive the same dietary advice as the diet group, but in addition they will receive help to increase their daily levels of physical activity.

Each participant will remain in the study for one year, whilst the study itself will last for three years. At the end of the study, we will be able to see whether exercise improves glucose control, blood pressure and cholesterol levels over and above that found with regular dietary advice or usual care.

Volunteer information sheet

The Early ACTID participant record book

What is the Early ACTID participant record book?

The Early ACTID participant record book contains participant consent forms, information about the study, and charts for recording clinical measurements. The Early ACTID record book that is given to participants in the two intervention groups will contain additional material:

Diet group: Information about diet, tasks to complete during nurse appointments, and charts to record their weight.

Diet plus exercise group: Information about diet and exercise, tasks to complete during nurse appointments, and charts to record weight and physical activity.

What is the purpose of the Early ACTID participant record book?

The participant record book is based on psychological theories for health behaviour change. Its purpose is to:

- Improve diabetes management by helping participants in the two intervention groups (Diet group and Diet plus exercise group) make healthy changes to their lifestyle.
- Facilitate patient involvement in their care during the study and improve the quality of care provided
- Improve communication between the participant and the Early ACTID healthcare professionals looking after them.

Why is it important for you to read through the materials?

- The Early ACTID study is committed to producing information for our participants that is clear, easy to read and of good quality.
- Feedback from people with diabetes will ensure that this information is user-friendly and relevant.

Instructions for reading through the materials

What will be involved?

- You will be provided with the written materials that will be given to participants when they enter the diet and exercise group of the Early ACTID study.
- We ask that you read through the materials and identify the following:
    - Words which are unclear or are unhelpful 'jargon'.
    - Phrases or sentences which are unclear or seem too long.
    - Diagrams and instructions which are unclear or seem unhelpful.
    - Instructions for tasks that are unclear or seem unhelpful.
    - Information that does not seem relevant to diabetes.
    - Information that does not follow in a logical order.
    - Writing that is too small and is difficult to read.

How will you provide feedback?

- You can write on the materials, or attach extra pages with your comments: whichever method you prefer.
- We recommend that you take approximately two weeks to look over the materials.
- We would like to see you again to discuss your comments and thoughts about the participant record book. We would be very happy to meet you at the University of Bristol, Tyndall Avenue, Clifton, Bristol. This can be at a time convenient for you. If meeting is not convenient for you, we can provide a pre-paid envelope for you to return the reviewed documents by post. Please find the address at the bottom of following page.

Are there any costs involved?

- As we mentioned previously, we are looking for volunteers. However, we are happy to reimburse any reasonable travel costs to and from the university for meetings.
- If you need to return the materials by post, we will provide a pre-paid envelope for you which does not require any stamps.
- What is really important to us is your time and contribution to this research project, which is invaluable to us.

What will happen with your comments?

- All returned comments and marked participant record books will be compiled and an analysis undertaken to establish if there are any commonly identified problems. Where possible, alterations to overcome problems will be made.

Important notes about the participant record book

- The version of the record book that has been given to you for reviewing differs from the final version that will be given to participants. The differences include:
    - Grey boxes at the top of some pages of your version. These boxes provide information for you that may help with the review process.
    - There are some pages that will appear in the final version, but have not been included in the version given to you. These include:
        - Information on healthy eating. These pages are still being developed and will be reviewed by other volunteers.
        - Duplicates of earlier pages in the booklet, which are in your version.
    - The final version of the record book will:
        - Be presented in an A5 ring binder.
        - Have some colour on each page.
        - Be built up throughout the duration of the study. At each appointment with the nurse and dietitian, participants will be given new pages to insert into the record book ring binder.

We would like to thank you for your interest in this study, and for volunteering your time to read through the materials. Your views are extremely important to us.

If you have any queries or wish to discuss any aspect of the materials, please contact Kate Fitzsimons:

Telephone: 07900 627412 or 0117 3311106

Email: K.Fitzsimons@bristol.ac.uk

Address: Department of Exercise and Health Sciences, University of Bristol, Tyndall Avenue, Bristol, BS8 1TP

Appendix 8. Standard operating procedure (SOP) developed by the researcher and used by nurses to deliver the intervention programmes

SOP for Nurse Visit 3/Week –2

Nurse objectives regarding diet and exercise

- Collect ActiGraph, diary sheet and exercise questionnaire.
- Provide participant record book (PRF) & visit 3 inserts. Discuss:
  - ⇒ Welcome & contact details
  - ⇒ Medication
  - ⇒ Early ACTID goals
  - ⇒ Food diary(x2) & instructions
  - ⇒ General health record
- Give participant opportunity to ask questions.

PRF materials required for visit 3:

- Participant Record File (PRF) ring binder
- PRF inserts

⇒ INFORMATION (ORANGE)

- ♦ Section divider & contents: Information (1 page)
- ♦ Sub-section front page: Information: Personal (1 page)
- ♦ I.1 Welcome & Contact details (1 page)
- ♦ I.3 Medication (1 page)
- ♦ I.5 Early ACTID goals (1 page)
- ♦ Sub-section front page: Information: Appointments (1 page)
- ♦ Sub-section front page: Information: Glossary (1 page)
- ♦ I.19-I.32. Glossary of terms (7 pages)

⇒ HEALTHY EATING (YELLOW)

- ♦ Section divider and contents: Healthy eating (1 page)
- ♦ Sub-section front page: Healthy Eating: Keeping track (1 page)
- ♦ HE.1 Recording your food intake with a diary (1 page)
- ♦ HE.3 Food diary: Sample (1 page)
- ♦ Sub-section front page: Healthy Eating: Food diary (1 page)
- ♦ HE.9 Food diary x2 (2 A4 pages)
- ♦ HE.11 Food and food associations (1 page)
- ♦ Sub-section front page: Healthy Eating: Goals and plans (1 page)
- ♦ Sub-section front page: Healthy Eating: Information sheets (1 page)

⇒ PROGRESS REPORTS (BLUE)

- ♦ Section divider & contents: Progress Reports (1 page)
- ♦ PR.1 General health record (1 page)

⇒ PERSONAL NOTES (PURPLE)

- ♦ Section divider & contents: Personal notes (1 page)
- ♦ PN.1-6 Personal notes (3 pages)

(Total inserts = 30)

Before the visit:

- Complete contact details on page I.2 of PRF

Full instructions: Visit 3 (Nurse)/ Week -2

1. Collect ActiGraph, diary sheet and exercise questionnaire.

- Ensure ActiGraph was positioned correctly in pouch (upright).
- Ensure correct ID and ActiGraph number are recorded on the diary sheet.
- Ensure participant has answered the questions at the bottom of the diary sheet.
- Ensure correct ID number is recorded on the exercise questionnaire.
- Ensure all exercise questions have been answered by participant.

2. Provide PRF and visit 3 inserts,

- Let participant know that the PRF is theirs to keep and that they are free to write notes and questions in it.

  ⇒ Advise participant that they will receive handouts at each session, which they will be helped with. These handouts should be kept in their PRF.

- Emphasise that it will be important in helping them reach their goals.
- Stress the importance of taking the PRF to all nurse and dietitian appointments throughout the study, but NOT to the doctor appointments.

2.1. Talk through the '*Welcome*' (I.1) and '*Contact details*' (I.2) inserts.

- Advise that the best way to contact you is by pager.

2.2. Complete the '*Medication*' (I.3) insert.

- Go through and complete '*Medication*' insert (I.3), recording their current medications. Alternatively, ask participant to complete this at home.

2.3. Discuss general '*Early ACTID goals*' (I.5).

- Talk through 'Early ACTID goals' insert (I.5).
- Mention that they will receive extra goals if allocated diet or diet plus exercise group.

2.4. Talk through the '*Food diary*' (HE.9-10 x2; HE.11) and keeping track instructions (HE.1-4).

- Use inserts the following inserts to explain how to complete the 4-day 'Food diary' (HE.9-10).
  - '*Recording your food intake with a diary*' (HE.1-2)
  - '*Food diary: Sample*' (HE.3-4)
- Talk through the '*Food and food associations*' (HE.11) insert and highlight the importance of recording ALL columns of the food diary.
- Ensure participant knows to record their food intake on 2 week days and 2 weekend days.
- Advise participant to keep the diary in their PRF and to take to Visit 4 to discuss with dietitian.

Briefly show participant '*General health record*' (PR.1) insert.

- Advise participant that completing the '*General health record*' is optional, but may be useful if they would like to record their test results.

3. Give participant opportunity to ask any questions.

SOP for Visit 5 (Nurse)/Week 2

Nurse objectives regarding diet and exercise

- Discuss what to expect in visit 5 with '***Appointments overview***' (I.16).
- Discuss key aspects of the nurse-participant relationship and sign the related agreement, '***Working together as a team***' (I.11-12).
- <u>Healthy eating</u>

  ⇒ Advise participant of option to monitor and record their weight using the chart (PR.3) and graph (PR.5). Use keeping track instruction inserts as guidelines (HE.5-HE.8).

  ⇒ Provide and go through healthy eating 'Information sheets' (HE.27-32).

  ⇒ Agree healthy eating goals for following 2 weeks, completing '***Healthy eating goals – agreed with your nurse***' (HE.17).

- <u>Physical activity</u>

  ⇒ Provide participant with pedometer and '***Pedometers***' (PA.1-2) insert.

  ⇒ Advise participant how to monitor and record daily physical activity using the keeping track section (PA.3-PA.8), '***Diary*** (PA.9-10) & '***Physical activity graph***' (PR.7) and they have at least 3 physical activity diaries.

  ⇒ Agree physical activity goals for following 2 weeks, completing '***Physical activity goals***' (PA.15).

  → Wear pedometer daily
  → Complete '***Physical activity diary***' daily
  → Complete '***Physical activity graph***' daily

  ⇒ Provide '***Troubleshooting your pedometer***' (PA.19-20) from the physical activity information sheets section.

- Give participant the opportunity to ask any questions.

SOP for Visit 5 (Nurse)/Week 2

Nurse objectives regarding diet and exercise

- Discuss what to expect in visit 5 with '***Appointments overview***' (I.16).
- Discuss key aspects of the nurse-participant relationship and sign the related agreement, '***Working together as a team***' (I.11-12).
- Healthy eating

  ⇒ Advise participant of option to monitor and record their weight using the chart (PR.3) and graph (PR.5). Use keeping track instruction inserts as guidelines (HE.5-HE.8).

  ⇒ Provide and go through healthy eating 'Information sheets' (HE.27-32).

  ⇒ Agree healthy eating goals for following 2 weeks, completing '***Healthy eating goals – agreed with your nurse***' (HE.17).

- Physical activity

  ⇒ Provide participant with pedometer and '***Pedometers***' (PA.1-2) insert.

  ⇒ Advise participant how to monitor and record daily physical activity using the keeping track section (PA.3-PA.8), '***Diary*** (PA.9-10) & '***Physical activity graph***' (PR.7) and they have at least 3 physical activity diaries.

  ⇒ Agree physical activity goals for following 2 weeks, completing '***Physical activity goals***' (PA.15).

  → Wear pedometer daily
  → Complete '***Physical activity diary***' daily
  → Complete '***Physical activity graph***' daily

  ⇒ Provide '***Troubleshooting your pedometer***' (PA.19-20) from the physical activity information sheets section.

- Give participant the opportunity to ask any questions.

Materials required for visit 5:

- Pedometer
- PRF inserts

⇒ **INFORMATION (ORANGE)**

- I.11 Working together as a team (1 page)

⇒ HEALTHY EATING (YELLOW)

- HE.5 Recording your weight (1 page)
- HE.7 Recording your weight on a graph (1 page)
- HE.9 Food diary x2 (2 A4 pages)
- HE.17 Healthy eating goals – agreed with your nurse (1 page)
- HE.27-32 Information sheets 'Reviewing your food diary' – 'Key points…' (3 pages)

⇒ **PHYSICAL ACTIVITY (RED)**

- Section divider & contents (2 pages)
- Sub-section front page: Physical activity: Keeping track (1 page)
- PA.1 Pedometers (1 page)
- PA.3 Recording your physical activity with a diary (1 page)
- PA.5 Physical activity diary: Sample (1 page)
- PA.7 Recording your physical activity on a graph (1 page)
- Sub-section front page: Physical activity: Diary (1 page)
- PA.9 Physical activity diary ≥3 (3 pages)
- Sub-section front page: Physical activity: Goals and plans (1 page)
- PA.15 Physical activity goals (1 page)
- Sub-section front page: Physical activity: Information sheets (1 page)
- PA.19 Troubleshooting your pedometer (1 page)
- Sub-section front page: Physical activity: Gaining confidence (1 page)

⇒ **PROGRESS REPORTS (BLUE)**

- PR.3 Weight chart (1 page)
- PR.5 Weight graph (1 page)
- PR.7 Physical activity graph (1 page)

(Total inserts = 28)

Before the visit:

- Check which group participant has been allocated

Full instructions: Visit 5 (Nurse)/Week 2

1. **Discuss what to expect in visit 5, using '*Appointments overview*' (I.16).**

- Advise participant what to expect
- Advise participant that they will have an opportunity to ask any questions

2. **Discuss key aspects of the nurse-participant relationship and sign the related agreement, '*Working together as a team*' (I.11-12).**

- State the nurse's responsibilities.
- State the participant's responsibilities.
- Ask if there are any other things that they would like to be added to either list.
- Suggest that you both sign as a way of remembering how you will work together.

3. **Healthy Eating**

3.1 Provide '*Recording your weight*' (HE.5) and '*Recording your weight on a graph*' (HE.7) and advise participant how to self-monitor weight.

- Talk participant through recording their weight each week on the '***Weight chart***' (PR.3) and '***Weight graph***' (PR.5).
- Advise participant that monitoring weight is optional, but emphasise that generally people who successfully lose weight and maintain their weight loss are those who tend to monitor their weight to keep track of their progress.

3.2 Provide healthy eating information sheets (HE.27-32).

- Talk through the following inserts:
  - '***Reviewing your food diary***' (HE.27)
  - '***Changing eating behaviours***' (HE28)
  - '***Setting goals***' (HE.29-31)
  - '***Key points to remember from this visit***' (HE.32)

3.3 Agree healthy eating goals with participant, using '*Healthy eating goals – agreed with your nurse*' (HE.17).

- Agree goals for the following 2 weeks.
- Ask participant to score their motivation and confidence for each goal
- Both sign the insert.
- Record agreed goals on the CRF.

4. Physical Activity

4.1. Provide participant with pedometer and '*Pedometers*' (PA.1-2) insert.

- Briefly explain what the pedometer is and how it works using '***Pedometers***' (PA.1-2).

4.2. Advise participant how to monitor and record their daily physical activity using the keeping track section PA.3-8, the '*Physical activity diary*' (PA.9-10) and the '*Physical activity graph*' (PR.7).

- Talk participant through '***Recording your physical activity***' (HE.3) and '***Physical activity diary: Sample***' (PA.5).
- Provide at least 3 '***Physical activity diary***' (PA.9-10) inserts and emphasise why it's important to complete and bring these to their next session:
    - People who keep track tend to be more active, and more successful at making lasting changes.
    - Early ACTID needs to know how much physical activity participants are doing so that we can determine dose-response. Also, it's important to see how participants are achieving their physical activity, i.e. are people doing 1 bout lasting 30 minutes, or 3 bouts of 10 minutes, and will this influence glucose and blood pressure control?
- Ensure participant is aware that only activity sessions lasting 10 minutes should be recorded.
- Ensure participant is happy using the physical activity diary
- Talk though '***Recording your physical activity on a graph***' (PA.7-8) and explain how to plot total daily steps.

4.3. Agree physical activity goals with participant, using '*Physical activity goals*' (PA.15).

- Agree and set goals for the following 2 weeks. These should be self-monitoring goals:

⇒ Wear pedometer during all waking hours

⇒ Keep daily physical activity diary of USUAL physical activity

⇒ Plot daily steps on '***Physical activity graph***' (PR.7)

- Ask participant to score their motivation and confidence for each goal.
- Both sign the insert.
- Record agreed goals on the CRF.

Provide '*Troubleshooting your pedometer*' (PA.19).

- Refer to '***Troubleshooting for your pedometer***' and advise participant to read this sheet if they encounter any problems with their pedometer.
- Advise that if the problem is not resolved, the participant should contact you by pager or email.

5. Give participant the opportunity to ask any other questions, perhaps about the study in general.

SOP for Visit 6 (Nurse)/Week 4

Nurse objectives regarding diet and exercise

- Weigh participant.
- Discuss what to expect in visit 6 with '***Appointments overview***' (I.16).
- Healthy Eating

  ⇒ Review and discuss previous '***Healthy eating goals – agreed with your nurse***' (HE.17), set at visit 5.

  ⇒ Review recent keeping track records (PR.3-5) (if appropriate).

  ⇒ Discuss and complete '***Successes and difficulties*** (HE.18).

  ⇒ Review information sheets provided by dietitian:
  - '***Healthy eating part II***' (HE.33-48).

  ⇒ Discuss '***Areas to focus on – agreed with your dietitian***' (HE.15).
- Physical activity

  ⇒ Review and discuss '***Physical activity goals***' (PA.15) set at visit 5.

  ⇒ Review completed '***Physical activity diary***' (PA.9-10) sheets and '***Physical activity graph***' (PR.7/8).

  ⇒ Discuss and complete '***Successes and difficulties***' (PA.16).

  ⇒ Provide and encourage participant to complete inserts for Gaining confidence subsection:
  - 'Physical activity history' (PA.33-34)
  - 'Benefits of physical activity' & 'Pros and cons' (PA35-36)

  ⇒ Provide inserts for Goals and plans subsection (PA.11-17).
  - '***Setting physical activity goals'*** (PA.11-12)
  - '***Other brisk activities***' (PA.13)

  ⇒ Agree '***Physical activity goals***' (PA.15) for following 2 weeks and agree a '***Physical activity plan***' (PA.17).

  → Something active on at least 3-4 days
  → 60 minutes over 6 days

  ⇒ Ensure participant has at least 3 '***Physical activity diary***' (PA.9-10) inserts.

  ⇒ Provide physical activity information sheets (PA.21-31).
- Schedule visit 7 for 2 weeks' time (week 6).

Full instructions: Visit (nurse) 6/Week 4

1. **Weigh participant.**

2. **Discuss what to expect in visit 6 with '*Appointments overview*' (I.16).**

3. **Healthy Eating**

3.1. Review and discuss previous '*Healthy eating goals – agreed with your nurse*' (HE.17), set at visit 5.

- With participant, briefly review goals set at visit 5.

3.2. Review keeping track records (PR.3-5) (if appropriate).

- If participant was intending to monitor their weight, ask how they got on with keeping track.
- Review their '***Weight chart***' (PR.3) and '***Weight graph***' (PR.5) to check records are being completed appropriately.
  - Congratulate on success with recording, if appropriate.
  - If participant is having difficulties, revise how to complete the records.
- Record on the CRF if participant is happy with completing the records. If participant has encountered problems, record on the CRF and state what these were.
- Record on the CRF what the self-monitored weekly weight was for previous weeks, as recorded on participant's 'Keeping track chart'.

3.3. Discuss and complete '*Successes and difficulties*' (HE.18).

- Ask participant how they have got on with reaching their healthy eating goals.
- Based on participant's response, and evidence from the keeping track records:
  - Congratulate on success with any improvement in healthy eating/weight.
  - If participant feels they have not made much effort, try saying 'tell me a little about that' and 'what would help you over the next few weeks?'
    - With participant, brainstorm how to resolve problems and record on insert.
  - Record on the CRF if participant has encountered problems, and what strategies have been discussed to resolve problems.
- Reinforce recent success/behavioural change.

3.4. Review information sheets provided by dietitian '*Healthy eating part II*' (HE.33-48).

- Ask participant if they have any questions about the information they received in their dietitian's appointment.

3.5. Discuss 'Areas to focus on – agreed with your dietitian' (HE.15) agreed with the dietitian.

- Ask participant how they intend to focus on these areas.

Full instructions: Visit (nurse) 6/Week 4

1. **Weigh participant.**

2. **Discuss what to expect in visit 6 with '*Appointments overview*' (I.16).**

3. **Healthy Eating**

3.1. Review and discuss previous '*Healthy eating goals – agreed with your nurse*' (HE.17), set at visit 5.

- With participant, briefly review goals set at visit 5.

3.2. Review keeping track records (PR.3-5) (if appropriate).

- If participant was intending to monitor their weight, ask how they got on with keeping track.
- Review their '***Weight chart***' (PR.3) and '***Weight graph***' (PR.5) to check records are being completed appropriately.
  - Congratulate on success with recording, if appropriate.
  - If participant is having difficulties, revise how to complete the records.
- Record on the CRF if participant is happy with completing the records. If participant has encountered problems, record on the CRF and state what these were.
- Record on the CRF what the self-monitored weekly weight was for previous weeks, as recorded on participant's 'Keeping track chart'.

3.3. Discuss and complete '*Successes and difficulties*' (HE.18).

- Ask participant how they have got on with reaching their healthy eating goals.
- Based on participant's response, and evidence from the keeping track records:
  - Congratulate on success with any improvement in healthy eating/weight.
  - If participant feels they have not made much effort, try saying 'tell me a little about that' and 'what would help you over the next few weeks?'
    - With participant, brainstorm how to resolve problems and record on insert.
  - Record on the CRF if participant has encountered problems, and what strategies have been discussed to resolve problems.
- Reinforce recent success/behavioural change.

3.4. Review information sheets provided by dietitian '*Healthy eating part II*' (HE.33-48).

- Ask participant if they have any questions about the information they received in their dietitian's appointment.

3.5. Discuss 'Areas to focus on – agreed with your dietitian' (HE.15) agreed with the dietitian.

- Ask participant how they intend to focus on these areas.

4. Physical activity

4.1. Review and discuss '*Physical activity goals*' (PA.15) agreed at visit 5.

- With participant, briefly review goals set at visit 5.

4.2. Review and discuss the 2 completed 'Physical activity diaries' and 'Physical activity graph'.

- Ask participant how they have got on with:
  - Using their pedometer.
  - Completing the 'Physical activity diary'.
  - Plotting their daily steps on the 'Physical Activity Graph'.
- Check the diary and the daily activity graph are being completed appropriately.

4.3. Discuss and complete '*Successes and difficulties*' (PA.16)

- Discuss successes and difficulties and record on insert.
- Congratulate on good completion, if appropriate.
- If participant is having difficulties, revise how to complete the records, and if necessary plot their steps on their 'physical activity graph' (PR.7-8).
- Record on the CRF if they were happy with completing the records. If they encountered problems, record on the CRF and state what these were.

4.4. Provide and complete inserts for Gaining confidence subsection:

- '***Physical activity history***' (PA.33-34)
  - Ask participant what physical activity they do in a typical week and record on the insert.
  - Ask about past activity behaviour and record on insert.
  - Ask about likes and dislikes and record on insert.
- '***Benefits of physical activity***' & '***Pros and cons***' (PA35-36)
  - Briefly talk through PA.35
  - Work through PA.36, encouraging participant to record their perceived pros and cons of increasing their physical activity.
  - Encourage participant to brainstorm strategies to minimise the cons.
  - Ask participant for consent to record these pros and cons on their CRF and take action accordingly.

4.5. Provide inserts for Goals and plans subsection (PA.11-17)

- '***Setting physical activity goals***' (PA.11-12)
  - Talk through PA11-12
  - Emphasise the importance of making small gradual increases over a number of weeks.
  - Advise that an additional 30 minutes of walking should approximately increase daily steps by 3000-3600.
- '***Other brisk activities***' (PA.13)
  - Encourage participant to tick those that they already do, or realistically could do.

4.6. Agree '*Physical activity goals*' (PA.15) for following 2 weeks and agree a '*Physical activity plan*' (PA.17).

- Discuss and agree suitable goals for following 2 weeks, until visit 7. Ideally, these should include:

  ⇒ Doing something active on 3 to 4 days over the following week

⇒ Doing 60 minutes of moderate-intensity activity over 6 days of the week after

- Ask participant how they intend to reach these goals, considering when, where and how they will be active.
- Encourage participant to develop an action plan using their '***Physical activity plan***' (PA.17-18) insert.
- Ask participant to record goals on the '***Physical activity goals***' (PA.15) insert.
- Ask participant to score their motivation and confidence for each goal.
- Record participant's weekly goals, motivation and confidence on the CRF and state whether the goals are on target (see above). If not on target, state why.

4.7. Ensure participant has at least 3 *'Physical activity diary'* (PA.9-10) inserts.

4.8. Provide physical activity information sheets (PA.21-31).

- Advise participant to look at these at home.

5. Schedule visit 7 for 2 weeks' time (week 6).

Visit 7 (Nurse)/Week 6

Nurse objectives regarding diet and exercise

- Weigh participant.
- Advise participant what to expect in visit 7, with '***Appointments overview***' (I.16).
- <u>Healthy eating</u>

  ⇒ Review and discuss previous '***Areas to focus on - agreed with your dietitian***' (HE.15), set at visit 6.

  ⇒ Review 'Keeping track' records (PR.3 & PR.5).

  ⇒ Discuss '***Successes and difficulties***'.

  ⇒ Provide and complete inserts for Information sheets subsection:
  - '***Triggers and cues for eating***' (PA.49-54)

  ⇒ Agree new '***Healthy eating goals - agreed with your nurse***' (HE.17) for following 2 weeks.
- <u>Physical activity</u>

  ⇒ Review and discuss '***Physical activity goals***' (PA.15) set at visit 6.

  ⇒ Review completed '***Physical activity diary***' (PA.9-10) sheets and '***Physical activity graph***' (PR.7/8).

  ⇒ Discuss '***Successes and difficulties***' (PA.16).

  ⇒ Use optional materials from 'Gaining confidence' subsection if participant has encountered difficulties and barriers.

  ⇒ Provide and encourage participant to complete inserts for 'Gaining confidence' subsection:
  - '***Lifestyle activity***'
  - '***Opportunities to be active***'

  ⇒ Agree '***Physical activity goals***' (PA.15) and a '***Physical activity plan***' (PA.17) for following 2 weeks.

  → Doing 90 minutes over 5 days or more for the following week

  → Doing 120 minutes over 5 days or more for the week after

  ⇒ Ensure participant has at least 3 '***Physical activity diary***' (PA.9-10) inserts.

  ⇒ Provide '***Physical activity graph***' (PR. 7-8), if appropriate.
- Schedule visit 8 for week 8.

Materials required for visit 7:

- PRF inserts

⇒ INFORMATION (ORANGE)

- N/A

⇒ HEALTHY EATING (YELLOW)

- HE.17-18 Healthy eating goals – agreed with your nurse (1 page)
- HE.49-54 Triggers and cues for eating (3 pages)

⇒ PHYSICAL ACTIVITY (RED)

- PA.9 Physical activity diary ≥3 (≤3 pages)
- PA.15 Physical activity goals (1 page)
- PA.17 Physical activity plan (1 page)
- PA.37 Lifestyle activity (1 page)
- PA.39 Opportunities to be active (1 page)
- PA.43-48* Barriers to physical activity* (3 pages)
- PA.49-52* Personal time diary* (2 pages)
- PA.53* People to help you achieve your goals* (1 page)
- PA.55* Local exercise opportunities* (1 page)

⇒ PROGRESS REPORTS (BLUE)

- PR.7 Physical activity graph (1 page)

(Total inserts = ≤20, of which 7 are optional)

* Optional inserts for helping participant to overcome perceived barriers

Before the visit:

- Review successes and difficulties identified in visit 6
- Review healthy eating and physical activity goals set at visit 6
- Enter physical activity diary data

Full instructions: Visit (nurse) 7/Week 6

1. Weigh participant.

2. Advise participant what to expect in visit 7, with '*Appointments overview*' (I.16).

3. Healthy eating

3.1. Review and discuss previous '*Areas to focus on - agreed with your dietitian*' (HE.15), set at visit 6.

- With participant, briefly review areas to focus on agreed with dietitian at visit 6.

3.2. Review 'Keeping track' records (PR.3-5) (if appropriate).

- If participant was intending to monitor their weight, ask how they got on with keeping track.
- Review their '***Weight chart***' (PR.3) and '***Weight graph***' (PR.5) to check records are being completed appropriately.
  - Congratulate on success with recording, if appropriate.
  - If participant is having difficulties, revise how to complete the records.
- Record on the CRF if participant is happy with completing the records. If participant has encountered problems, record on the CRF and state what these were.
- Record on the CRF what the self-monitored weekly weight was for previous weeks, as recorded on participant's 'Keeping track chart'.

3.3. Discuss 'Successes and difficulties'.

- Ask participant how they have got on with reaching their healthy eating goals.
- Based on participant's response, and evidence from the keeping track records:
  - Congratulate on success with any improvement in healthy eating/weight.
  - If participant feels they have not made much effort, try saying 'tell me a little about that' and 'what would help you over the next few weeks?'
    - With participant, brainstorm how to resolve problems and record on insert.
  - Record on the CRF if participant has encountered problems, and what strategies have been discussed to resolve problems.
- Reinforce recent success/behavioural change.

3.4. Provide and complete inserts for Information sheets subsection:

- '***Triggers and cues for eating***' (PA.49-54)

3.5. Agree new 'Healthy eating goals - agreed with your nurse' (HE.17) for following 2 weeks.

- Discuss and agree healthy eating goals for the following 2 weeks until visit 8.
- Ask participant how they intend to reach these goals.
- Ask participant to record goals on insert '***Healthy eating goals***' (HE.17).
- Ask participant to score their motivation and confidence for each goal.
- Record participant's weekly goals and their motivation and confidence on the CRF.

4. Physical activity

4.1. Review and discuss '*Physical activity goals*' (PA.15) set at visit 6.

- With participant, briefly review goals set at visit 6.

4.2. Review completed '*Physical activity diary*' (PA.9-10) sheets and '*Physical activity graph*' (PR.7/8).

- Ask participant how they have got on with:
  - Using their pedometer.
  - Completing the 'Physical activity diary'.
  - Plotting their daily steps on the 'Physical Activity Graph'.
- Check the diary and the daily activity graph are being completed appropriately.

4.3. Discuss 'Successes and difficulties' (PA.16).

- Congratulate on success with any increase in physical activity.
- Ask participant to record any successes on the insert. These can include wearing their pedometer during waking hours, completing the 'Keeping track' records, any increase in physical activity, reaching their physical activity goal (Total weekly minutes).
- Record these successes on the CRF.
- If participant has not reached goals or feels they have not made much effort, try saying 'tell me a little about that' and 'What would help you over the next few weeks?'
- Ask participant to record any difficulties on the insert.
- Record these difficulties on the CRF.

4.4. Use optional materials from 'Gaining confidence' subsection if participant has encountered difficulties and barriers.

- If participant is having difficulties increasing barriers, use the optional materials to overcome barriers:

⇒ '*Barriers to physical activity*'* (PA.43-48)

⇒ '*Personal time diary*'* (PA.49-52)

⇒ '*People to help you achieve your goals*'* (PA.53)

⇒ '*Local exercise opportunities*'* (PA.55)

- Record on the CRF which inserts were used.

4.5. Provide and complete inserts for 'Gaining confidence' subsection:

- '*Lifestyle activity*' (PA.37)
  - Ask participant to consider any changes they could make, swapping inactive choices for active choices, e.g. taking the stairs instead of the lift or escalator. Encourage participant to complete the table on PA.38.
  - Use '*Opportunities to be active*' for ideas
- '*Opportunities to be active*' (PA.39)
  - Encourage participant to tick those that are realistic.

4.6. Agree '*Physical activity goals*' (PA.15) and a '*Physical activity plan*' (PA.17) for following 2 weeks.

- Discuss and agree suitable goals for following 2 weeks, until visit 8. Ideally, these should include:

⇒ Doing 90 minutes over 5 days or more for the following week

⇒ Doing 120 minutes over 5 days or more for the week after

- Ask participant how they intend to reach these goals, considering when, where and how they will be active.
- Encourage participant to develop an action plan using their '***Physical activity plan***' (PA.17-18) insert.
- Ask participant to record goals on the '***Physical activity goals***' (PA.15) insert.
- Ask participant to score their motivation and confidence for each goal.
- Record participant's weekly goals, motivation and confidence on the CRF and state whether the goals are on target (see above). If not on target, state why.

4.7. Ensure participant has at least 3 '*Physical activity diary*' (PA.9-10) inserts.

4.8. Provide '*Physical activity graph*' (PR. 7-8), if appropriate.

5. Schedule visit 8 for week 8

Visit 8 (Nurse)/Week 8

Nurse objectives regarding diet and exercise

- Weigh participant.
- Advise participant what to expect in visit 8, with '***Appointments overview***' (I.16-17).
- <u>Healthy eating</u>

  ⇒ Review and discuss previous '***Healthy eating goals- agreed with your nurse***' (HE.17), set at visit 7.

  ⇒ Review 'Keeping track' records (PR.3 & PR.5)

  ⇒ Discuss '***Successes and difficulties***' (HE.18).

  ⇒ Provide and complete inserts for Information sheets subsection:
    - '***Relapses and coping with difficult situations***' (HE.55-60)

  ⇒ Agree new '***Healthy eating goals - agreed with your nurse***' (HE.17) for following 6 weeks

  ⇒ Provide food diary x2

- <u>Physical activity</u>

  ⇒ Review and discuss '***Physical activity goals***' (PA.15) set at visit 7.

  ⇒ Review completed '***Physical activity diary***' (PA.9-10) sheets and '***Physical activity graph***' (PR.7/8).

  ⇒ Discuss '***Successes and difficulties***' (PA.16).

  ⇒ Use optional materials from 'Gaining confidence' subsection if participant has encountered difficulties and barriers.

  ⇒ Provide and encourage participant to complete inserts for 'Gaining confidence' subsection:
    - '***Lapses***' (PA.41-42)

  ⇒ Agree '***Physical activity goals***' (PA.15) and a '***Physical activity plan***' (PA.17) for following 6 weeks.
    → Doing 150 minutes over 5 days or more for the following week
    → At least 150 minutes over 5 days or more thereafter

  ⇒ Ensure participant has at least 6 '***Physical activity diary***' (PA.9-10) inserts.

  ⇒ Provide '***Physical activity graph***' (PR. 7-8), if appropriate.

- Schedule telephone call for week 10.
- Schedule visit 9 for week 14.

Materials required for visit 8:

- PRF inserts

⇒ **INFORMATION (ORANGE)**

- ♦ N/A

⇒ HEALTHY EATING (YELLOW)

- ♦ HE.17-18 Healthy eating goals – agreed with your nurse (1 page)
- ♦ HE.55-60 Relapses and coping with difficult situations (3 pages)
- ♦ HE.9 Food diary x2 (2 A4 pages)

⇒ **PHYSICAL ACTIVITY (RED)**

- ♦ PA.9 Physical activity diary >6 (6 pages)
- ♦ PA.15 Physical activity goals (1 page)
- ♦ PA.17 Physical activity plan (1 page)
- ♦ PA.41 Preventing relapses (1 page)
- ♦ PA.43-48* Barriers to physical activity* (3 pages)
- ♦ PA.49-52* Personal time diary* (2 pages)
- ♦ PA.53* People to help you achieve your goals* (1 page)
- ♦ PA.55* Local exercise opportunities* (1 page)

⇒ **PROGRESS REPORTS (BLUE)**

- ♦ PR.7 Physical activity graph (1 page)

(Total inserts = 23, of which 7 are optional)

* Optional inserts for helping participant to overcome perceived barriers

Before the visit:

- Review successes and difficulties identified in visit 7
- Review healthy eating and physical activity goals set at visit 7
- Enter physical activity diary data

Full instructions: Visit (nurse) 8/Week 8

1. Weigh participant.

2. Advise participant what to expect in visit 8, with '*Appointments overview*' (I.16-17).

3. Healthy eating

3.1. With participant, briefly review goals set at visit 7.

- Review and discuss previous '*Healthy eating goals- agreed with your nurse*' (HE.17), set at visit 7

3.2. Review 'Keeping track' records (PR.3 & PR.5)

- If participant was intending to monitor their weight, ask how they got on with keeping track.
- Review their '***Weight chart***' (PR.3) and '***Weight graph***' (PR.5) to check records are being completed appropriately.
  - Congratulate on success with recording, if appropriate.
  - If participant is having difficulties, revise how to complete the records.
- Record on the CRF if participant is happy with completing the records. If participant has encountered problems, record on the CRF and state what these were.
- Record on the CRF what the self-monitored weekly weight was for previous weeks, as recorded on participant's 'Keeping track chart'.

3.3. Discuss 'Successes and difficulties' (HE.18).

- Ask participant how they have got on with reaching their healthy eating goals.
- Based on participant's response, and evidence from the keeping track records:
  - Congratulate on success with any improvement in healthy eating/weight.
  - If participant feels they have not made much effort, try saying 'tell me a little about that' and 'what would help you over the next few weeks?'
    - With participant, brainstorm how to resolve problems and record on insert.
  - Record on the CRF if participant has encountered problems, and what strategies have been discussed to resolve problems.
- Reinforce recent success/behavioural change.

3.4. Provide and complete inserts for Information sheets subsection:

- 'Relapses and coping with difficult situations' (HE.55-60)

3.5. Agree new 'Healthy eating goals - agreed with your nurse' (HE.17) for following 6 weeks

- Discuss and agree healthy eating goals for the following 6 weeks until visit 9.
- Ask participant how they intend to reach these goals.
- Ask participant to record goals on insert '***Healthy eating goals***' (HE.17).
- Ask participant to score their motivation and confidence for each goal.
- Record participant's weekly goals and their motivation and confidence on the CRF.

3.6. Provide food diary x2

4. Physical activity

4.1. Review and discuss '*Physical activity goals*' (PA.15) set at visit 7.

- With participant, briefly review goals set at visit 7.

4.2. Review completed '*Physical activity diary*' (PA.9-10) sheets and '*Physical activity graph*' (PR.7/8).

- Ask participant how they have got on with:
  - Using their pedometer.
  - Completing the 'Physical activity diary'.
  - Plotting their daily steps on the 'Physical Activity Graph'.
- Check the diary and the daily activity graph are being completed appropriately.

4.3. Discuss 'Successes and difficulties' (PA.16).

- Congratulate on success with any increase in physical activity.
- Ask participant to record any successes on the insert. These can include wearing their pedometer during waking hours, completing the 'Keeping track' records, any increase in physical activity, reaching their physical activity goal (Total weekly minutes).
- Record these successes on the CRF.
- If participant has not reached goals or feels they have not made much effort, try saying 'tell me a little about that' and 'What would help you over the next few weeks?'
- Ask participant to record any difficulties on the insert.
- Record these difficulties on the CRF.

4.4. Use optional materials from 'Gaining confidence' subsection if participant has encountered difficulties and barriers.

- If participant is having difficulties increasing barriers, use the optional materials to overcome barriers:

⇒ '***Barriers to physical activity***'* (PA.43-48)

⇒ '***Personal time diary***'* (PA.49-52)

⇒ '***People to help you achieve your goals***'* (PA.53)

⇒ '***Local exercise opportunities***'* (PA.55)

- Record on the CRF which inserts were used.

4.5. Provide and encourage participant to complete inserts for 'Gaining confidence' subsection:

- '***Lapses***' (PA.41-42)

4.6. Agree '*Physical activity goals*' (PA.15) and a '*Physical activity plan*' (PA.17) for following 6 weeks.

- Discuss and agree suitable goals for following 6 weeks, until visit 9. Ideally, these should include:

⇒ Doing an extra 150 minutes over 5 days or more for the following week

⇒ At least an extra 150 minutes over 5 days or more thereafter

- SOP for Visit 8 continued
- Ask participant how they intend to reach these goals, considering when, where and how they will be active.
- Encourage participant to develop an action plan using their '***Physical activity plan***' (PA.17-18) insert.
- Ask participant to record goals on the '***Physical activity goals***' (PA.15) insert.
- Ask participant to score their motivation and confidence for each goal.

- Record participant's weekly goals, motivation and confidence on the CRF and state whether the goals are on target (see above). If not on target, state why.

4.7. Ensure participant has at least 6 '*Physical activity diary*' (PA.9-10) inserts.

4.8. Provide '*Physical activity graph*' (PR. 7-8), if appropriate.

5. Schedule telephone call for week 10.

6. Schedule visit 9 for week 14.

Visit 9 (Nurse)/Week 9

Nurse objectives regarding diet and exercise

- Weigh participant.
- Advise participant what to expect in visit 9, with '***Appointments overview***' (I.16-17).
- <u>Healthy eating</u>

  ⇒ Review and discuss previous '***Healthy eating goals- agreed with your nurse***' (HE.17), set at visit 8.

  ⇒ Review 'Keeping track' records (PR.3 & PR.5)

  ⇒ Discuss '***Successes and difficulties***' (HE.18).

  ⇒ Review information sheets provided by dietitian:
  - '***Portion sizes and food labels***' (HE.61-72)

  ⇒ Discuss 'Areas to focus on – agreed with your dietitian' (HE15).

- <u>Physical activity</u>

  ⇒ Review and discuss '***Physical activity goals***' (PA.15) set at visit 8.

  ⇒ Review completed '***Physical activity diary***' (PA.9-10) sheets and '***Physical activity graph***' (PR.7/8).

  ⇒ Discuss '***Successes and difficulties***' (PA.16).

  ⇒ Use optional materials from 'Gaining confidence' subsection if participant has encountered difficulties and barriers.

  ⇒ Agree '***Physical activity goals***' (PA.15) and a '***Physical activity plan***' (PA.17) for following 6 weeks.
  → At least 150 minutes over and above BL

  ⇒ Ensure participant has at least 6 '***Physical activity diary***' (PA.9-10) inserts.

  ⇒ Provide '***Physical activity graph***' (PR. 7-8), if appropriate.

- Schedule visit 10 for week 20.

Materials required for visit 9:

- PRF inserts

⇒ **INFORMATION (ORANGE)**

- ♦ N/A

⇒ HEALTHY EATING (YELLOW)

- ♦ N/A

⇒ **PHYSICAL ACTIVITY (RED)**

- ♦ PA.9 Physical activity diary >6 (6 pages)
- ♦ PA.15 Physical activity goals (1 page)
- ♦ PA.17 Physical activity plan (1 page)
- ♦ PA.43-48* Barriers to physical activity* (3 pages)
- ♦ PA.49-52* Personal time diary* (2 pages)
- ♦ PA.53* People to help you achieve your goals* (1 page)
- ♦ PA.55* Local exercise opportunities* (1 page)

⇒ **PROGRESS REPORTS (BLUE)**

- ♦ PR.7 Physical activity graph (1 page)

(Total inserts = 16, of which 7 are optional)

* Optional inserts for helping participant to overcome perceived barriers

Before the visit:

- Review successes and difficulties identified in visit 8
- Review healthy eating and physical activity goals set at visit 8
- Enter physical activity diary data

Full instructions: Visit (nurse) 9/Week 9

1. **Weigh participant.**

2. **Advise participant what to expect in visit 9, with '*Appointments overview*' (I.16-17).**

3. **Healthy eating**

3.1. With participant, briefly review goals set at visit 8.

- Review and discuss previous '*Healthy eating goals- agreed with your nurse*' (HE.17), set at visit 8.

3.2. Review 'Keeping track' records (PR.3 & PR.5).

- If participant was intending to monitor their weight, ask how they got on with keeping track.
- Review their '***Weight chart***' (PR.3) and '***Weight graph***' (PR.5) to check records are being completed appropriately.
  - Congratulate on success with recording, if appropriate.
  - If participant is having difficulties, revise how to complete the records.
- Record on the CRF if participant is happy with completing the records. If participant has encountered problems, record on the CRF and state what these were.
- Record on the CRF what the self-monitored weekly weight was for previous weeks, as recorded on participant's 'Keeping track chart'.

3.3. Discuss 'Successes and difficulties' (HE.18).

- Ask participant how they have got on with reaching their healthy eating goals.
- Based on participant's response, and evidence from the keeping track records:
  - Congratulate on success with any improvement in healthy eating/weight.
  - If participant feels they have not made much effort, try saying 'tell me a little about that' and 'what would help you over the next few weeks?'
    - With participant, brainstorm how to resolve problems and record on insert.
  - Record on the CRF if participant has encountered problems, and what strategies have been discussed to resolve problems.
- Reinforce recent success/behavioural change.

3.4. Review information sheets *'Portion sizes and food labels'* (HE.61-72) provided by dietitian.

- Ask participant if they have any questions about the information they received in their dietitian's appointment.

3.5. Discuss 'Areas to focus on – agreed with your dietitian' (HE15).

- Ask participant how they intend to focus on these areas.

4. Physical activity

4.1. Review and discuss '*Physical activity goals*' (PA.15) set at visit 8.

- With participant, briefly review goals set at visit 8.

4.2. Review completed '*Physical activity diary*' (PA.9-10) sheets and '*Physical activity graph*' (PR.7/8).

- Ask participant how they have got on with:
  - Using their pedometer.
  - Completing the 'Physical activity diary'.
  - Plotting their daily steps on the 'Physical Activity Graph'.
- Check the diary and the daily activity graph are being completed appropriately.

4.3. Discuss 'Successes and difficulties' (PA.16).

- Congratulate on success with any increase in physical activity.
- Ask participant to record any successes on the insert. These can include wearing their pedometer during waking hours, completing the 'Keeping track' records, any increase in physical activity, reaching their physical activity goal (Total weekly minutes).
- Record these successes on the CRF.
- If participant has not reached goals or feels they have not made much effort, try saying 'tell me a little about that' and 'What would help you over the next few weeks?'
- Ask participant to record any difficulties on the insert.
- Record these difficulties on the CRF.

4.4. Use optional materials from 'Gaining confidence' subsection if participant has encountered difficulties and barriers.

- If participant is having difficulties increasing barriers, use the optional materials to overcome barriers:

⇒ '*Barriers to physical activity*'* (PA.43-48)

⇒ '*Personal time diary*'* (PA.49-52)

⇒ '*People to help you achieve your goals*'* (PA.53)

⇒ '*Local exercise opportunities*'* (PA.55)

- Record on the CRF which inserts were used.

4.5. Agree '*Physical activity goals*' (PA.15) and a '*Physical activity plan*' (PA.17) for following 6 weeks.

- Discuss and agree suitable goals for following 6 weeks, until visit 10. Ideally, these should include:

⇒ At least 150 minutes over and above what was done at BL.

- Ask participant how they intend to reach these goals, considering when, where and how they will be active.
- Encourage participant to develop an action plan using their '*Physical activity plan*' (PA.17-18) insert.
- Ask participant to record goals on the '*Physical activity goals*' (PA.15) insert.
- Ask participant to score their motivation and confidence for each goal.

- Record participant's weekly goals, motivation and confidence on the CRF and state whether the goals are on target (see above). If not on target, state why.

4.6. Ensure participant has at least 6 '*Physical activity diary*' (PA.9-10) inserts.

4.7. Provide '*Physical activity graph*' (PR. 7-8), if appropriate.

5. Schedule visit 10 for week 20.

Visit 10 (Nurse)/Week 10

Nurse objectives regarding diet and exercise

- Weigh participant.
- Advise participant what to expect in visit 10, with '***Appointments overview***' (I.16-17).
- <u>Healthy eating</u>

  ⇒ Review and discuss previous '***Areas to focus on - agreed with your dietitian***' (HE.15), set at visit 9.

  ⇒ Review 'Keeping track' records (PR.3 & PR.5)

  ⇒ Discuss '***Successes and difficulties***'.

  ⇒ Provide and complete inserts for Information sheets subsection:
  - '***Eating and shopping habits***' (HE.73-75)
- Agree new '***Healthy eating goals - agreed with your nurse***' (HE.17) for following 8 weeks.
- <u>Physical activity</u>

  ⇒ Review and discuss '***Physical activity goals***' (PA.15) set at visit 9.

  ⇒ Review completed '***Physical activity diary***' (PA.9-10) sheets and '***Physical activity graph***' (PR.7/8).

  ⇒ Discuss '***Successes and difficulties***' (PA.16).

  ⇒ Use optional materials from 'Gaining confidence' subsection if participant has encountered difficulties and barriers.

  ⇒ Agree '***Physical activity goals***' (PA.15) and a '***Physical activity plan***' (PA.17) for following weeks.

  → At least and extra 150 minutes over 5 days

  ⇒ Ensure participant has at least 8 '***Physical activity diary***' (PA.9-10) inserts.

  ⇒ Provide '***Physical activity graph***' (PR. 7-8), if appropriate.
- Ensure participant has 6-month fitness test booked.
- Schedule visit 12 for week 28.

Materials required for visit 10:

- PRF inserts

⇒ INFORMATION (ORANGE)

- ♦ N/A

⇒ HEALTHY EATING (YELLOW)

- ♦ HE.17-18 Healthy eating goals – agreed with your nurse (1 page)
- ♦ HE.73-75 Eating and shopping habits (2 pages)

⇒ PHYSICAL ACTIVITY (RED)

- ♦ PA.9 Physical activity diary ≥6 (6 pages)
- ♦ PA.15 Physical activity goals (1 page)
- ♦ PA.17 Physical activity plan (1 page)
- ♦ PA.43-48* Barriers to physical activity* (3 pages)
- ♦ PA.49-52* Personal time diary* (2 pages)
- ♦ PA.53* People to help you achieve your goals* (1 page)
- ♦ PA.55* Local exercise opportunities* (1 page)

⇒ PROGRESS REPORTS (BLUE)

- ♦ PR.7 Physical activity graph (1 page)

(Total inserts = 19, of which 7 are optional)

* Optional inserts for helping participant to overcome perceived barriers

Before the visit:

- Review successes and difficulties identified in visit 9
- Review healthy eating and physical activity goals set at visit 9
- Enter physical activity diary data

Full instructions: Visit (nurse) 10/Week 20

1. **Weigh participant.**

2. **Advise participant what to expect in visit 9, with '*Appointments overview*' (I.16-17).**

3. **Healthy eating**

3.1. Review and discuss previous '*Areas to focus on - agreed with your dietitian*' (HE.15), set at visit 9.

- With participant, briefly review areas to focus on agreed with dietitian.

3.2. Review 'Keeping track' records (PR.3 & PR.5).

- If participant was intending to monitor their weight, ask how they got on with keeping track.
- Review their '***Weight chart***' (PR.3) and '***Weight graph***' (PR.5) to check records are being completed appropriately.
  - Congratulate on success with recording, if appropriate.
  - If participant is having difficulties, revise how to complete the records.
- Record on the CRF if participant is happy with completing the records. If participant has encountered problems, record on the CRF and state what these were.
- Record on the CRF what the self-monitored weekly weight was for previous weeks, as recorded on participant's 'Keeping track chart'.

3.3. Discuss 'Successes and difficulties'.

- Ask participant how they have got on with reaching their healthy eating goals.
- Based on participant's response, and evidence from the keeping track records:
  - Congratulate on success with any improvement in healthy eating/weight.
  - If participant feels they have not made much effort, try saying 'tell me a little about that' and 'what would help you over the next few weeks?'
    - With participant, brainstorm how to resolve problems and record on insert.
  - Record on the CRF if participant has encountered problems, and what strategies have been discussed to resolve problems.
- Reinforce recent success/behavioural change.

3.4. Provide and complete inserts for Information sheets subsection:

- '***Eating and shopping habits***' (HE.73-75).

3.5. Agree new 'Healthy eating goals - agreed with your nurse' (HE.17) for following 8 weeks.

- Discuss and agree healthy eating goals for the following 8 weeks until visit 12.
- Ask participant how they intend to reach these goals.
- Ask participant to record goals on insert '***Healthy eating goals***' (HE.17).
- Ask participant to score their motivation and confidence for each goal.
- Record participant's weekly goals and their motivation and confidence on the CRF.

Full instructions: Visit (nurse) 10/Week 20

1. **Weigh participant.**

2. **Advise participant what to expect in visit 9, with '*Appointments overview*' (I.16-17).**

3. **Healthy eating**

3.1. Review and discuss previous '*Areas to focus on - agreed with your dietitian*' (HE.15), set at visit 9.

- With participant, briefly review areas to focus on agreed with dietitian.

3.2. Review 'Keeping track' records (PR.3 & PR.5).

- If participant was intending to monitor their weight, ask how they got on with keeping track.
- Review their '***Weight chart***' (PR.3) and '***Weight graph***' (PR.5) to check records are being completed appropriately.
  - Congratulate on success with recording, if appropriate.
  - If participant is having difficulties, revise how to complete the records.
- Record on the CRF if participant is happy with completing the records. If participant has encountered problems, record on the CRF and state what these were.
- Record on the CRF what the self-monitored weekly weight was for previous weeks, as recorded on participant's 'Keeping track chart'.

3.3. Discuss 'Successes and difficulties'.

- Ask participant how they have got on with reaching their healthy eating goals.
- Based on participant's response, and evidence from the keeping track records:
  - Congratulate on success with any improvement in healthy eating/weight.
  - If participant feels they have not made much effort, try saying 'tell me a little about that' and 'what would help you over the next few weeks?'
    - With participant, brainstorm how to resolve problems and record on insert.
  - Record on the CRF if participant has encountered problems, and what strategies have been discussed to resolve problems.
- Reinforce recent success/behavioural change.

3.4. Provide and complete inserts for Information sheets subsection:

- '***Eating and shopping habits***' (HE.73-75).

3.5. Agree new 'Healthy eating goals - agreed with your nurse' (HE.17) for following 8 weeks.

- Discuss and agree healthy eating goals for the following 8 weeks until visit 12.
- Ask participant how they intend to reach these goals.
- Ask participant to record goals on insert '***Healthy eating goals***' (HE.17).
- Ask participant to score their motivation and confidence for each goal.
- Record participant's weekly goals and their motivation and confidence on the CRF.

4. Physical activity

4.1. Review and discuss '*Physical activity goals*' (PA.15) set at visit 9.

- With participant, briefly review goals set at visit 9.

4.2. Review completed '*Physical activity diary*' (PA.9-10) sheets and '*Physical activity graph*' (PR.7/8).

- Ask participant how they have got on with:
  - Using their pedometer.
  - Completing the 'Physical activity diary'.
  - Plotting their daily steps on the 'Physical Activity Graph'.
- Check the diary and the daily activity graph are being completed appropriately.

4.3. Discuss 'Successes and difficulties' (PA.16).

- Congratulate on success with any increase in physical activity.
- Ask participant to record any successes on the insert. These can include wearing their pedometer during waking hours, completing the 'Keeping track' records, any increase in physical activity, reaching their physical activity goal (Total weekly minutes).
- Record these successes on the CRF.
- If participant has not reached goals or feels they have not made much effort, try saying 'tell me a little about that' and 'What would help you over the next few weeks?'
- Ask participant to record any difficulties on the insert.
- Record these difficulties on the CRF.

4.4. Use optional materials from 'Gaining confidence' subsection if participant has encountered difficulties and barriers.

- If participant is having difficulties increasing barriers, use the optional materials to overcome barriers:

⇒ '*Barriers to physical activity*'* (PA.43-48)

⇒ '*Personal time diary*'* (PA.49-52)

⇒ '*People to help you achieve your goals*'* (PA.53)

⇒ '*Local exercise opportunities*'* (PA.55)

- Record on the CRF which inserts were used.

4.5. Agree '*Physical activity goals*' (PA.15) and a '*Physical activity plan*' (PA.17) for following 8 weeks.

- Discuss and agree suitable goals for following 6 weeks, until visit 10. Ideally, these should include:

⇒ At least 150 minutes over and above what was done at BL.

- Ask participant how they intend to reach these goals, considering when, where and how they will be active.
- Encourage participant to develop an action plan using their '*Physical activity plan*' (PA.17-18) insert.
- Ask participant to record goals on the '*Physical activity goals*' (PA.15) insert.
- Ask participant to score their motivation and confidence for each goal.

- Record participant's weekly goals, motivation and confidence on the CRF and state whether the goals are on target (see above). If not on target, state why.

4.6. Ensure participant has at least 8 '*Physical activity diary*' (PA.9-10) inserts.

4.7. Provide '*Physical activity graph*' (PR. 7-8), if appropriate.

5. Ensure participant has 6-month fitness test booked for week 26.

6. Schedule visit 12 for week 28.

Appendix 9. An example of the physical activity database which is used to assess compliance with the physical activity study goal

Example of week 5 data entry sheet on the database

WEEK 5
Walking

Day of week Time monitor on Time monitor off	Time (hrs:mins)				Steps				Targets achieved?	
	Start of session	End of session	Duration of session	Total per day	Start of session	End of session	Total per session	End of day	Time	Steps
Monday	07:40	07:56	00:16	00:44			0	6790	No	No
Time Monitor on	15:15	15:43	00:28				0			
Time Monitor off			00:00				0			
			00:00				0			
Tuesday	08:27	08:46	00:19	00:39			0	5248	No	No
Time Monitor on	17:30	17:50	00:20				0			
Time Monitor off			00:00				0			
			00:00				0			
Wednesday	12:05	12:55	00:50	00:50			0	7300	No	No
Time Monitor on			00:00				0			
Time Monitor off			00:00				0			
			00:00				0			
Thursday	13:30	13:50	00:20	00:52			0	9464	No	Yes
Time Monitor on	15:10	15:42	00:32				0			
Time Monitor off			00:00				0			
			00:00				0			
Friday	08:20	08:48	00:28	00:28			0	3542	No	No
Time Monitor on			00:00				0			
Time Monitor off			00:00				0			
			00:00				0			
Saturday	10:00	10:38	00:38	01:20			0	11690	Yes	Yes
Time Monitor on	11:40	12:22	00:42				0			
Time Monitor off			00:00				0			
			00:00				0			
Sunday	15:50	16:56	01:06	01:06			0	9543	Yes	Yes
Time Monitor on			00:00				0			
Time Monitor off			00:00				0			
			00:00				0			
TOTALS	**Weekly total (hrs:mins)**			**05:59**	**Weekly total (steps)**			**53577**	**Yes**	**Yes**

	hrs:mins	Steps	
No. of days walking was recorded in diary	7	7	
BASELINE VALUES FROM VISIT 6	hrs:mins	Steps	
Weekly total (Walking)	03:23	38536	
Daily average (Walking)	00:29	5505	
LONG-TERM GOALS SET AT VISIT 6			
Weekly target is at least an extra	02:30	15000	
Daily target is an extra	00:30	3000	on at least 5/7 days
Weekly target amounts to a total of	05:53	53536	
Daily target amounts to a total of	00:59	8505	on at least 5/7 days
CURRENT AMOUNT OF WALKING			
Weekly total (Walking)	05:59	53577	
Daily average (Walking)	00:51	7654	
DIFFERENCE BETWEEN BASELINE & CURRENT LEVELS			
Weekly difference (Current-BL values)	02:36	15041	
Daily difference (Current-BL values)	00:22	2149	

Example of the summary sheet on the database

WEEK SINCE RANDOMISATION	BL at 2/3	Targets	4	5	6
TIME SPENT BRISK WALKING					
Total time spent per week (hrs:mins)	03:23	05:53	05:54	05:59	05:33
Average time spent per day (hrs:mins)	00:29	00:59	00:50	00:51	00:47
No. of days time target achieved (≥ extra 30mins)	N/A	≥ 5/7	2	2	2
Difference between weekly current & BL values (hrs:mins)	N/A	N/A	02:31	02:36	02:10
Difference between daily current & BL values (hrs:mins)	N/A	N/A	00:21	00:22	00:18
ACCUMULATED STEPS					
Total steps per week	38536	53536	50099	53577	45908
Average steps per day	5505	8505	7157	7654	7651
No. of days step target achieved	N/A	≥ 5/7	2	3	3
Difference between weekly current & BL values	N/A	N/A	11563	15041	7372
Difference between daily current & BL values	N/A	N/A	1652	2149	2146
TIME SPENT DOING OTHER MODERATE ACTIVITIES					
Total time spent per week (hrs:mins)	01:29	N/A	01:40	01:00	01:50
Average time spent per day (hrs:mins)	00:12	N/A	00:14	00:08	00:15
Difference between weekly current & BL values (hrs:mins)	N/A	N/A	00:11	######	00:21
Difference between daily current & *BL values*	N/A	N/A	00:01	######	00:03

Appendix 10. Participant information sheets: *Physical activity*

University of BRISTOL

Early ACTID Study
Joint Clinical Research Unit
Level 5 Old Building, near Ward 29
Bristol Royal Infirmary
Marlborough Street
BRISTOL BS2 8HW

Tel: +44 (0117) 9282440
Fax: +44 (0117) 9284470
E mail: Early-ACTID@bristol.ac.uk

Participant Information Sheet

ActiGraph Activity Monitor

What is an ActiGraph activity monitor?

An ActiGraph activity monitor is a small electronic device that will measure your physical activity by continually monitoring and recording the movements of the body.

What is the purpose of the activity monitor?

This study aims to investigate the effect of physical activity on glucose level, blood pressure and cholesterol in people who have type 2 diabetes. To determine these effects, it is important that we accurately measure your physical activity at the start of the study, and then at 6 months and 1 year, so we can monitor any changes to your activity level.

How does the activity monitor measure my physical activity?

When worn securely on your waist with an elastic belt, the ActiGraph activity monitor moves only as your body moves. When in the correct upright position, components inside the monitor are able to record the range of your movements using units called counts. The ActiGraph then sums the counts every 60 seconds to provide minute-by-minute information about your level of activity.

How do I wear the ActiGraph monitor?

The ActiGraph monitor is enclosed in a pouch that is worn on either an elastic belt around your waist, which should be adjusted to the appropriate size for you, or your own personal belt. The ActiGraph monitor should be positioned on your hip, as shown in the picture. You may wear the elastic belt either under or over the top of your clothing. In order for the ActiGraph to measure your physical activity accurately, it is important that you keep it upright, and held snugly against your body.

When should I wear the ActiGraph monitor?

The ActiGraph monitor should be worn during ALL waking hours, from the start of your day until just before bed. The ActiGraph is **not waterproof** however, so you should remove it whilst washing or swimming.

You should start wearing the ActiGraph as soon as you get up on the day after your fitness assessment. We need information about your physical activity level for 1 full week, so you should continue to wear the ActiGraph monitor for 7 consecutive days.

Once you have worn it for seven full days, please take the ActiGraph off and keep it in a safe place until you return it to the nurse at your next Early ACTID appointment. It is important that we have this information before you start the trial, so **please remember to take the ActiGraph with you to your baseline measurement appointment with the nurse.**

How will the ActiGraph monitor know when to start recording my activity?

The ActiGraph has been pre-programmed to start recording your activity from 5am the morning after your fitness assessment, unless alternative arrangements have been agreed.

Should I change my activity level during the 7 days whilst wearing the ActiGraph monitor?

It is very important that the information collected by your ActiGraph monitor reflects your USUAL level of physical activity, so please maintain your USUAL lifestyle whilst wearing the monitor.

Do I need to do anything else whilst wearing the ActiGraph monitor?

Your ActiGraph comes with a diary sheet, which you should use to record any physical activity you do that the ActiGraph is unable to record or accurately measure, i.e. water-based activities such as swimming, or seated exercise such as cycling. This is important so we do not miscalculate your activity level. **Please return your completed diary sheet with the ActiGraph to your nurse at the next appointment.**

Troubleshooting

What happens if I get the ActiGraph wet?

The ActiGraph is NOT waterproof, so please try not to get it wet.

What should I do if I forget to put the ActiGraph on?

Please put the ActiGraph on as soon as you remember, and then record the time on your diary sheet.

If you have problems with your ActiGraph, please contact Kate Fitzsimons:

Telephone: 0117 3311106

Email: K.Fitzsimons@bristol.ac.uk

Instructions for recording your physical activity on the diary sheet

- The diary sheet should be completed every day during the seven days that you wear your ActiGraph monitor.
- The following information should be recorded:
  - ⇒ The day of the week.
  - ⇒ The date.
  - ⇒ The time you put the ActiGraph monitor on at the start of the day.
  - ⇒ The time you start an activity session that CAN NOT be recorded or accurately measured by the ActiGraph monitor, i.e. when it is removed during water-based activities, or worn during seated exercise of a moderate intensity (e.g. cycling).
  - ⇒ The type of activity you are doing, e.g. swimming, aqua aerobics, cycling etc.
  - ⇒ The duration of the activity not recorded or accurately measured by the ActiGraph monitor (in minutes).
  - ⇒ The time you take the ActiGraph monitor off at the end of the day.

Here is an example

Day	Weekday	Date	Time ActiGraph put on	Time activity started	Activity not recorded or accurately measured by ActiGraph monitor	Duration of activity (mins)	Time ActiGraph taken off
1	Thursday	17/11/05	07:30	16:00	Swimming	20	22:00
2	Friday	18/11/05	07:45				22:20
2	Saturday	19/11/05	09:25	11:00	Cycling	10	23:45

KEY POINTS

- ☐ **Do not remove the ActiGraph from its pouch once you start wearing it.**
- ☐ **Wear the ActiGraph over your right hip during ALL waking hours, putting it on as soon as you get up, and removing it just before you go to bed.**
- ☐ **Wear the ActiGraph for 7 consecutive days.**
- ☐ **Maintain your usual lifestyle whilst wearing the ActiGraph.**
- ☐ **Return the ActiGraph and diary sheet (2nd page only) to your next Early ACTID appointment.**
- ☐ **If the ActiGraph falls out of the pouch make sure you replace it the correct way up, with the black button in the top left corner, as shown in the picture on the first page.**

Office use

AG ☐ Date _____

Diary ☐ Date _____

Initialised start day: _____

Initialised start date: _____

Physical activity ActiGraph diary ID: _____ ActiGraph #: _____ Site: _____ Visit _____

Please ONLY record physical activities that can NOT be recorded or accurately measured by your ActiGraph monitor, e.g. water-based activities or seated exercise of a moderate intensity, such as cycling.

Day	Weekday	Date	Time ActiGraph put on	Time activity started	Activity not recorded or accurately measured by ActiGraph monitor	Duration of activity (mins)	Time ActiGraph taken off
1							
2							
3							
4							
5							
6							
7							

Does your activity during the last 7 days reflect your usual level of physical activity? ☐ Yes ☐ No

If no, were you: (Please tick one box) ☐ More active than usual ☐ Less active than usual

Appendix 11. ActiGraph data reduction protocol

ActiGraph data processing

Macro

- Run macro
  - Path (w:\data\TT\act)
  - Start name (eg. 1606)
  - End name (e.g. 1609)
  - Countif value [2100 = cut point for MVPA (moderate to vigorous physical activity)]

Sheet labelled 'Raw'

- Raw data from running macro

Sheet labelled 'Raw + time'

- Insert hourly time in 1st column

Sheet labelled 'Cases by days'

- Insert new column for Day
- Time in 2nd column
- Highlight in yellow the row representing the start of each day (5AM) (days 1-7)
- Highlight in red the representing the start of each day (days 8+)
- Cases grouped by 1st Day of wearing AG

Sheet labelled 'Mon Aligned'

- Cut and paste cases to appropriate start day
- Cut and paste data to start at Monday

Sheet labelled 'Daily sum data'

- Insert 4 rows at the end of each day
- Row 1: Sum for 24hrs the total counts and minutes of MVPA (=SUM(C3:C26))
- Row 2: Count the number of hours the ActiGraph was worn (=COUNTIF(C3:C26,">0"))
- Row 3: Mean counts per hour(=Total counts/Number of hours worn) and minutes of MVPA (=Total minutes of MVPA/Number of hours worn)

Sheet labelled 'Daily sum data+Clean'

- On days where AG was worn for <10hrs, replace all hourly counts and MVPA with '0'
- '0' = missing data for counts

Sheet labelled 'Cleaned sum only'

- Copy and paste special 'values' the Daily sum data+Clean

Sheet labelled 'Sum grpd'

- Align counts and mvpa into one column (Copy and paste data beneath, then delete first counts column and shift cells left. Delete all MVPA columns as duplicate data)
- Group data by category, e.g. Mon Sum, Tues Sum, Wed Sum; Mon Hrs worn, Tues Hrs worn, Wed Hrs worn.

Sheet labelled 'Sum grpd trans'

- Copy and paste special 'transposed' Sum grpd data

Sheet labelled 'MVPA missing'

- 2 copies of Sum grpd trans (one beneath the other)
- In mvpa and mvpaph cells of 2nd copy, use IF function for coding MVPA as '999' when daily summed counts = 0 (=IF(D4=0[Daily counts],"999",AE4[mvpa]) (999 will show in mvpa for days that AG was worn for <10hrs)

Sheet labelled 'SPSS ready'

- MVPA missing data copied and pasted special as values
- Ready to paste into SPSS.

Appendix 12. Participant information sheets: Fitness

University of BRISTOL

Early ACTID Study
Joint Clinical Research Unit
Level 5 Old Building, near Ward 29
Bristol Royal Infirmary
Marlborough Street
BRISTOL BS2 8HW

Tel: +44 (0117) 9282440
Fax: +44 (0117) 9284470
E mail: Early-ACTID@bristol.ac.uk

Participant Information Sheet
Fitness Assessment
Bristol

What is fitness?

We would like you to take part in a test to determine how fit you are. Your fitness level (also known as cardiorespiratory or aerobic fitness) is a measure of how easily your blood and lungs deliver fuel to the muscles during exercise. A person's level of fitness is a good indicator of health, as being fit protects against the development of many diseases, including coronary heart disease, obesity, type 2 diabetes mellitus (T2DM) and some forms of cancer.

What is the purpose of the fitness assessment?

Although we know that people who are physically active and/or fit are less likely to develop diabetes, we do not know how important these factors are in people who already have diabetes. By measuring your fitness and physical activity over the course of the study we will be able to find out how important each of these factors are in helping you to manage your glucose control, blood pressure and cholesterol levels.

How will my fitness level be measured?

We will ask you to walk as briskly as you can for 1 mile on an indoor track. During the test you will wear a monitor to record your heart rate, and we will measure how long it takes you to walk the mile. If you are unable to walk for 1 mile, we will calculate your level of fitness based on the time it takes you to walk ¼ or ½ mile, whichever is the furthest distance you cover.

What will happen at the fitness assessment appointment?

When you arrive, the person carrying out the assessment will take you to the area where the test will take place. Prior to the test, they will talk you through exactly what is required and answer any questions that you may have. Providing you are happy to go ahead with the test, you will be given a heart rate monitor to wear. This is a watch that you wear on your wrist and an elastic belt that is worn next to your skin around your chest. The watch displays your heart rate, which is transmitted from the belt.

When you are ready to begin, you will be asked to warm up by walking round one lap of the track, gradually picking up the pace. At various points, you will be asked to rate how hard you feel you are exercising (see page 8), so that we can establish an appropriate walking pace that is tailored to your own personal ability. Once you cross the start line after the warm-up lap, we will start timing. At the end of each lap, we will let you know the number of laps you have completed and ask you to read aloud the heart rate displayed on the watch. Once you have finished, you will be advised to walk at a slower pace to cool down and allow your heart rate to stabilise.

At the end of this appointment, you will be provided with an activity monitor to wear for 7 consecutive days. You will also be given a physical activity diary and an exercise questionnaire to complete at home. These items should be returned to your nurse at your next visit.

How long will my appointment take?

Your appointment should take between 30 and 40 minutes. Please allow longer if you will be using the changing and shower facilities.

What should I bring to the appointment?

Please arrive wearing casual clothing and comfortable, **supportive shoes appropriate for walking a long distance.** We also advise that you bring some water to stay hydrated and a small snack for afterwards, e.g. a banana. If you have asthma and use an inhaler, please bring it with you.

What should I do to prepare for the assessment?

To prepare for the fitness assessment, we would like you to:

- Maintain your usual level of physical activity prior to the assessment.
- Drink plenty of fluids over the 24-hour period before the test.
- Get an adequate amount of sleep (6-8 hours) the night before the test.
- Avoid exercise or strenuous physical activity the day of the test.
- Avoid tobacco, alcohol, and caffeine for 3 hours prior to the test.
- Have a light snack 2-3 hours before the test, avoiding anything too heavy that might cause indigestion.
- Read the **'Rating how hard you are exercising'** sheet on page 8, so that you are familiar with the scale when you arrive for your appointment.

Are there any risks involved with the assessment?

If you are unused to walking briskly, you may notice some muscle tenderness in the days following the assessment. This is normal, and is caused by your muscles recovering after working harder than usual.

Where will the assessment take place?

Your fitness assessment will take place on the **indoor track** at the:
Centre for Sport, Exercise and Health, University of Bristol
Tyndall Avenue
Clifton
Bristol, BS8 1TP

What facilities will be available?

Changing and Shower facilities

- There will be changing and shower facilities available at the centre.

Food

- There is a Chandos Deli on the ground floor of the centre, which sells a selection of sandwiches, wraps, salads, snacks, and hot and cold drinks.

Parking

- There is (limited) pay and display car parking outside and nearby the Centre for Sport, Exercise and Health. A free parking space outside Hawthorns (a 1-2 minute walk from the Centre) can be arranged for the duration of your appointment, although this MUST be booked in advance. If this is required, your nurse will give you a parking certificate that should be clearly displayed in your vehicle for the duration of your fitness appointment. If your nurse has given you a certificate, please park in either the forecourt or at the rear of Hawthorns (this is labelled on the precinct map).
- There are bike racks to secure bicycles, mopeds and motorbikes at the side of the building.

How can I get to the Centre for Sport, Exercise and Health?

A map of the University precinct is attached on page 4. The entrance to the Centre for Sport, Exercise and Health is on Tyndall Avenue (4F on precinct map, see arrow).

By Car

A map of Bristol is attached on page 5.

From the M32 Exit the M4 at junction 19 marked for the M32. Follow the M32 into Bristol. The motorway terminates a few hundred metres from a major T junction. Carry straight on from the end of the motorway and turn right at the junction (following signs to Bus Station and Clifton). You will come to a roundabout where you should take the second exit (following signs to Bus Station, Royal Infirmary and Clifton). Go straight on over several sets of traffic lights. Just after the entrance to the multi storey car park on your left, turn right into Woodland Road. At the top of the hill you will see Hawthorns on your left. Pre-booked parking is available in either the forecourt or at the rear of Hawthorns.

By Bus

There is a free Hospital and University Shuttle Bus for staff and visitors that runs between Bristol Temple Meads Train Station, the city centre, Bristol General Hospital and Bristol Royal Infirmary, and the University of Bristol. It operates a continuous service between the hours of 06.30-17.45 on Monday to Friday, with a frequency of between 10 and 24 minutes. A timetable and route map is attached on pages 6 and 7. The stop closest to the Centre for Sport, Exercise and Health is just outside Hawthorns and is numbered 10 on the route map.

Frequent local buses also run regularly from Temple Meads Train Station, Broadmead, and the City Centre to the top of Park Street (6D on precinct map/Opposite Brown's Restaurant) and Elton Road, outside the Hawthorns (4E on precinct map) (Bus service 9/9A).

By Train

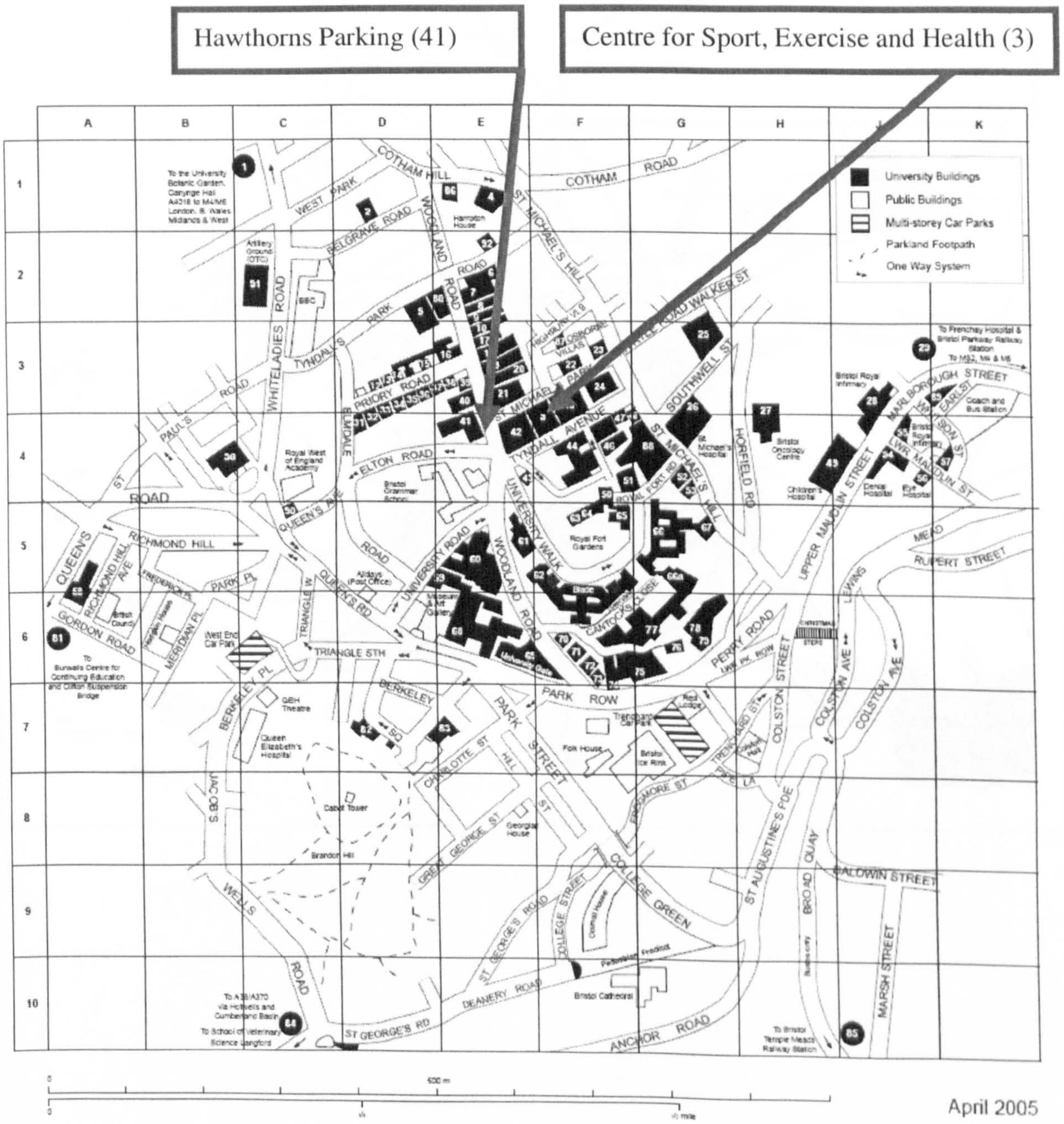
The Centre for Sport, Exercise and Health is approximately 1.6 miles away from Temple Meads Train Station and 6 miles from Parkway station. For information on local trains, please call National Rail Enquiries on 08457 48 49 50.

For further information on planning your journey, please call Travel Line on 0870 608 2 608, or log on to http://www.travelbristol.org/

What should I do if I have further questions about the fitness assessment?

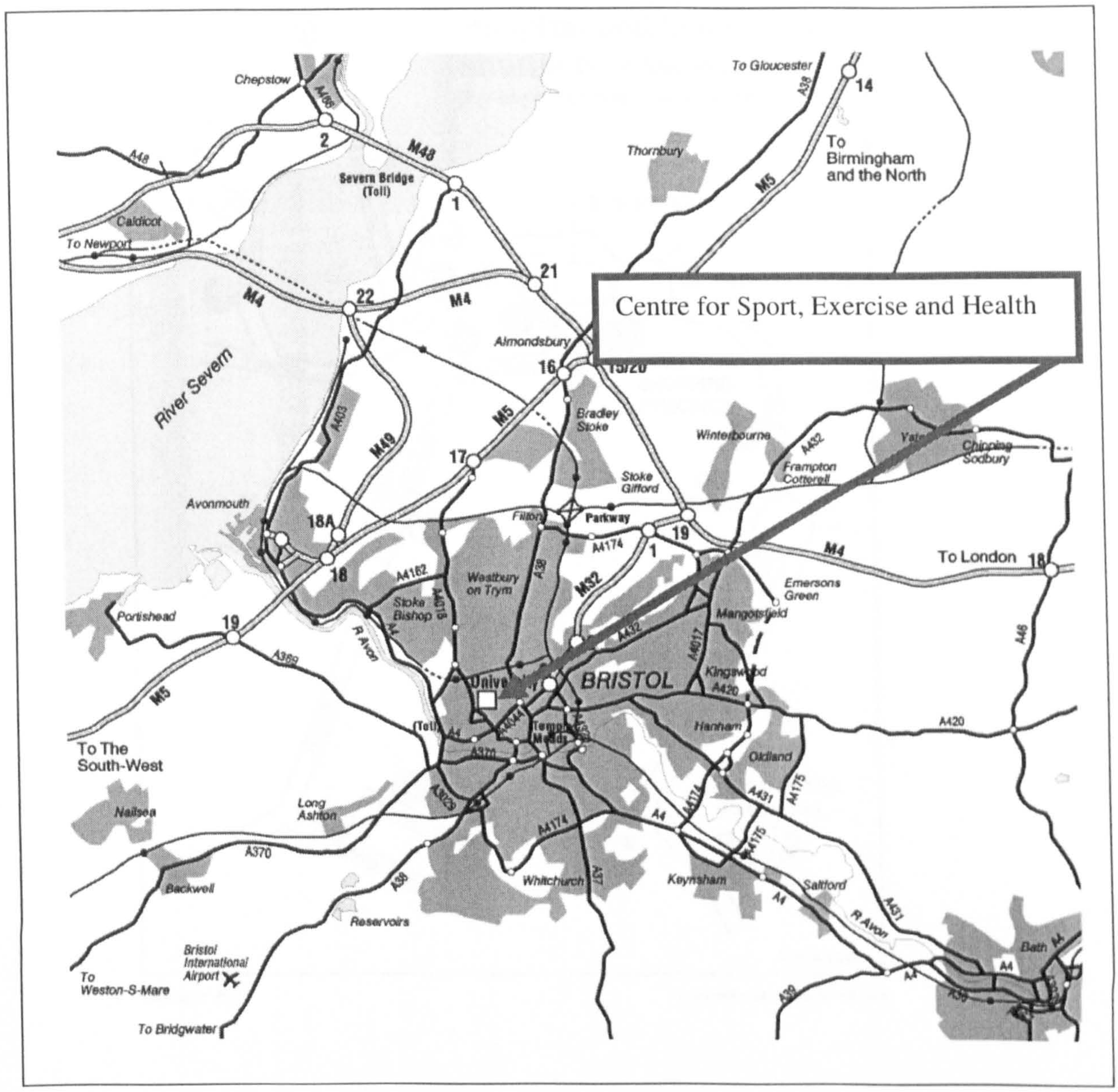
If you have further questions, or need to cancel or reschedule your fitness appointment, please contact your Early ACTID nurse, or **Kate Fitzsimons** by telephone (0117 3311106) or email (K.Fitzsimons@bristol.ac.uk).

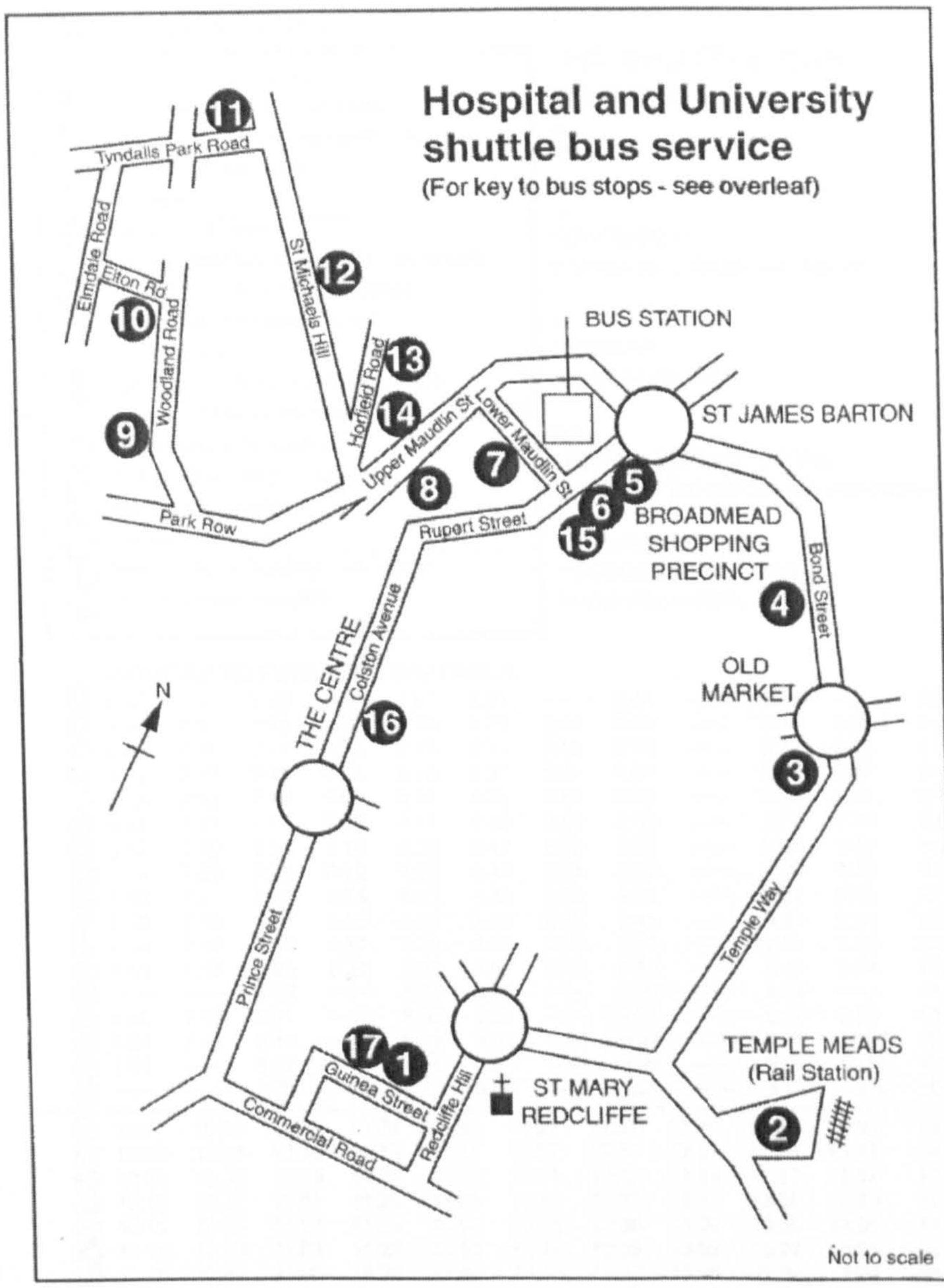
Map of University of Bristol Precinct



April 2005

Map of Bristol





October 2004

The Hospital & University Free Bus Shuttle

for patients, visitors and staff of the UBHT hospitals
and staff and visitors of the University of Bristol

United Bristol Healthcare NHS
NHS Trust

KEY TO BUS STOPS

1. Bristol General Hospital
2. Bristol Temple Meads rail station
3. Temple Way (for Central Health Clinic)
4. New Primark/Old C&A
5. Debenhams
6. House of Fraser
7. Bus station/Dental and Eye Hospitals
8. BRI (opposite main entrance)
9. Bottom of Woodland Road
10. The Hawthorns
11. Tyndalls Park Children's Centre (also for Bristol Homoeopathic Hospital)
12. St Michael's Hospital
13. Bristol Oncology Centre
14. BRI (main entrance)
15. House of Fraser
16. Bristol & West building - city centre
17. Bristol General Hospital

core route

THE SHUTTLE BUS SERVICE

is
FREE

is
CONVENIENT
6.30am to 5.45pm weekdays

is
REGULAR
every 24 minutes

has
MORE CHOICE OF STOPS
including Temple Meads rail station

and will help to
REDUCE CONGESTION
in the city centre.

MONDAY TO FRIDAYS TIMETABLE

1	6:37	—	7:33	—	7:57	8.21	—	8.45	—	9:09	—	9:33
2	—	7:12	7:43	8.00	8:10	8:30	8:40	8:55	—	9:19	9.30	9:43
3	6:41	7:15	7:47	8:03	8:13	8:35	8:45	8:59	—	9:23	9.35	9:47
4	6:42	7:17	7:49	8:05	8:15	8:37	8 47	9:01	—	9:25	9.37	9:49
5	6:43	7:18	7:50	8:06	8:16	8:38	8.48	9:02	—	9:26	9.38	9:50
6	6:44	7:19	7.51	8:07	8:17	8:39	8:49	9.03	—	9:27	9:39	9:51
7	6:47	7:22	7:54	8:10	8:20	8:42	8:52	9:06	—	9:30	9.42	9.54
8	—	7:23	7:55	8:12	8:22	8:44	8:54	9:07	—	9:31	9:43	9:55
9	6:49	7:28	8:01	8:15	8:25	8:45	8:55	9:13	—	9:37	9:49	10:01
10	6:50	7:30	8.03	8:17	8:27	8:49	8:59	9:15	—	9:39	9:51	10:03
11	6.52	7:32	8.05	8:19	8.29	8:51	9.01	9:17	—	9:41	9:53	10:05
12	6:53	7:33	8:06	8:20	8.30	8.52	9.02	9.18	—	9:42	9.54	10:06
13	—	—	8:08	—	8:32	8.56	—	9:20	—	9:44	—	10.08
14	6:56	7:37	8:11	—	8:35	8.59	—	9:23	—	9:47	9:59	10:11
15	6:59	7:41	8:15	—	8:39	9 03	—	9:27	—	9:51	10:03	10:15
16	7:01	—	8:17	—	8:41	9.05	—	9.29	—	9:53	10:05	10:17
17	—	—	8:21	—	8:45	9.09	—	9:33	—	9:57	10:09	10:21

1	9.57	10:21	10:45	11:09	11:33	11:57	12:21	12:45	13.09	13:33	13:57
2	10.07	10.31	10:55	11:19	11:43	12:07	12:31	12.55	13:19	13:43	14:07
3	10:11	10:35	10:59	11:23	11:47	12:11	12:35	12:59	13:23	13:47	14:11
4	10:13	10:37	11:01	11:25	11:49	12:13	12:37	13.01	13:25	13:49	14:13
5	10:14	10:38	11:02	11:26	11:50	12:14	12:38	13:02	13:26	13:50	14:14
6	10:15	10:39	11:03	11:27	11:51	12:15	12:39	13:03	13:27	13:51	14:15
7	10:18	10:42	11:06	11:30	11:54	12:18	12:42	13:06	13:30	13:54	14:18
8	10:19	10:43	11.07	11:31	11:55	12:19	12:43	13.07	13:31	13:55	14:19
9	10:25	10:49	11:13	11:37	12:01	12:25	12:49	13:13	13:37	14:01	14:25
10	10:27	10:51	11:15	11:39	12:03	12:27	12:51	13:15	13:39	14:03	14:27
11	10:29	10:53	11:17	11:41	12:05	12:29	12:53	13:17	13:41	14.05	14:29
12	10:30	10.54	11:18	11:42	12:06	12:30	12:54	13:18	13:42	14.06	14:30
13	10:32	—	11:20	11:44	12:08	12:32	—	13:20	—	14.08	—
14	10:35	10.59	11:23	11:47	12:11	12:35	12:59	13.23	13:47	14:11	14:35
15	10:39	11:03	11:27	11:51	12.15	12:39	13:03	13:27	13:51	14:15	14:39
16	10:41	11:05	11:29	11:53	12:17	12:41	13.05	13:29	13.53	14:17	14:41
17	10:45	11:09	11:33	11:57	12:21	12:45	13:09	13:33	13:57	14.21	14:45

1	14:21	14:45	15:09	15:21	15:45	16:00	16:09	16:33	—	16:57	—
2	14:31	14:55	15:19	15:31	15:55	16:05	16:19	16:50	17:00	17:07	17:30
3	14:35	14:59	15:23	15:35	15:59	16:09	16:23	16:54	—	17:11	—
4	14:37	15:01	15.25	15:37	16:01	16:11	16.25	16:56	—	17:13	—
5	14:38	15:02	15.26	15:38	16.02	16:12	16:26	16.57	—	17:14	—
6	14:39	15:03	15:27	15:39	16:03	16:13	16:27	16:58	—	17:15	—
7	14:42	15.06	15:30	15:42	16:06	16:16	16:30	17:01	—	17:18	—
8	14:43	15:07	15:31	15:43	16:07	16:18	16:31	17:06	—	17:19	—
9	14:49	15:13	15:37	15:49	16:13	16:21	16:37	17:10	—	17:25	—
10	14.51	15:15	15:39	15:51	16:15	16:30	16:39	17:12	—	17:27	—
11	14:53	15:17	15:41	15:53	16:17	16:32	16:41	17:14	—	17:29	—
12	14:54	15:18	15:42	15:54	16:18	16:33	16:42	17:15	—	17:30	—
13	14:56	15:20	—	15:56	16:20	—	16:44	—	—	—	—
14	14:59	15:23	15:47	15:59	16:23	16:38	16.47	17:18	—	17:35	—
15	15.03	15:27	15.51	16:03	16:27	16:42	16:51	17:22	—	17:39	—
16	15:05	15:29	—	16:05	16:29	16.45	16:53	17:24	—	BTM*	—
17	15:09	15:33	—	16:09	16:33	—	16:57	—	17:15	17:45	17:40

*These services will stop at Bristol Temple Meads after House of Fraser

Rating how hard you are exercising

During the fitness test, we would like you to rate how hard you feel you are working. This rating should reflect how heavy and strenuous the exercise feels to you, both physically and mentally.

During the warm-up lap, and then throughout the walk test, we will ask you to rate how you feel on the scale of 6-20. This will give you a good idea of the intensity level of your activity, and you can use this information to speed up or slow down your pace to reach the desired range.

During the walk test, we would like you to be working between 13 and 15 on this scale.

Please familiarise yourself with this scale before your appointment.

SCALE	EFFORT %	DESCRIPTION	EXAMPLE
6	20	Very, very light	Rest
7	30		
8	40		
9	50	Very light	Gentle walking
10	55		
11	60	Fairly light	
12	65		
13	70	**Somewhat hard**	**A steady pace – OK to continue**
14	75		
15	80	**Hard**	
16	85		
17	90	Very hard	You can go on, but you have to push yourself – You feel very tired
18	95		
19	100	Very, very hard	The most strenuous exercise you have ever experienced
20	Exhaustion	Maximal exertion	You can not go on

Appendix 13. Standard operating procedure used to administer 1-mile walk fitness tests

Fitness test: 1 mile (1609m) walk test

Locations

Bristol: Centre for Sport, Exercise and Health (Mondays & Wednesdays)
Cost: Free
Indoor track: 118.4meters

- **1 mile/1609m = [13.5895 laps] 13 laps (1539.2m) + 69.8m**

Taunton: Wellington Leisure Centre (Every other Thursday 1am-3pm)
Cost: £40/hr (2hrs every other week) = £2080 per annum / £6240 for 3 years
Studio –

- **1 mile/1609m = [27.74 laps] 27 laps (1566m) + 43meters**

Gloucester: GL1 Centre (Every other Tuesday 10am-1pm)
Cost: Free
Martial arts room: 11.2x14.5m = 47m perimeter

- **1 mile/1609.3m = [34.24 laps] 35 laps (1645m) + 35.7 meters**

Items required for test

Equipment

- 2 Polar heart rate monitor transmitters, 2 receiver watches and multiple straps
- Digital stop watch with split and lap timing
- Clip board
- Initialised ActiGraph monitor(s), elastic belt(s) & pouch(es)
- Sterile wipes
- Seating

Paperwork

- Appointment diary
- Standard Operating Procedure (SOP)
- RPE Scale
- Fitness test data entry sheet
- ActiGraph participant information sheet and diary + instructions
- Exercise Questionnaires

Food and drink

- Water and plastic cups
- Glucose tablets

Data required for predicted VO_2max regression equation:

- Weight
- Age
- Gender
- 1-mile walk time
- Post exercise heart rate

VO_2max Equation:

132.853 - (0.0769 × Weight) - (0.3877 × Age) + (6.315 × Gender) - (3.2649 × Time) - (0.1565 × Heart rate)[NB. Gender: Female=0; Male=1]

Before participant arrives:

1. Charge and initialise ActiGraph monitor & record monitor number & participant details
2. Complete Data entry sheet with participant details provided by nurse
3. Advise reception of participant appointments
4. Ensure all equipment is to hand
5. Ensure you have the means to request emergency help (e.g. emergency phone, radio etc.)

Before the test:

1. **Confirm '*Participant information*'** on data entry form.
2. **Complete '*Health and safety*'** section on data entry form.
   - → Has participant eaten within the last 3 hours?
   - → Is participant wearing appropriate footwear?
   - → Is there any other relevant information you should discuss with participant?
3. **Provide Polar Heart Rate monitor**
   - → Dampen the electrodes of the Polar transmitter strap and ask participant to put this on next to the skin around the chest. Assist if necessary.
   - → Ask participant to put the receiver watch on their wrist and check the heart rate is being monitored correctly. If the watch is too small, ask participant to hold the watch instead.
   - → Ensure participant knows to read out HR from watch at the end of each lap and also when asked to do so. If participant is unable to do this, confirm that they should display the watch so that you can read it after each lap (note that participant should continue to walk briskly).
4. **Complete *'1-mile walk test preparation'*** section on data entry form
   - → Is the HR monitor worn correctly and working
   - → Who will read the HR during the 1-mile walk
   - → Does participant understand the following:
     - ♦ The '***Rating how hard you are exercising***' sheet and scale, given in their fitness information pack.
     - ♦ How hard they should be exercising during the test, i.e. between 13 and 15 on the scale.
     - ♦ How to signal if they need assistance, or to stop the test for any reason during the test. (Ensure participant understands that if they feel unwell or want to stop the test at any point they should raise their hand. Explain that you will go over to where the participant is and assist them.)
     - ♦ How many laps they are required to walk to cover the 1-mile distance.
     - ♦ The finish point and cool-down procedure (1-2 laps at slower pace, followed by optional stretches).
5. Confirm participant is happy to proceed with the test.

Warm-up lap:

1. Advise participant that you will walk a warm-up lap together, gradually building up the pace.
2. Begin the warm-up lap.
3. **Ask participant for RPE** towards end of lap and ***record*** on data entry form. Advise participant of appropriate pace for the 1-mile, relative to the warm-up. (i.e. to increase pace to reach 13-15 on scale)
4. Briefly stop before starting test and encourage participant to walk on the spot to maintain heart rate.
5. **Record the '*post warm-up HR*'** on data entry form.
6. **Record *'Time started'*** on data entry form.
7. Check participant is ok to start.

Instructions for carrying out the test:

1. Advise participant they are free to begin and you will start the stopwatch when they cross the start line.
2. Press the 'start' button on the stopwatch as soon as participant's foot crosses the line.
3. At the end of each lap, simultaneously:

   → **Press the stopwatch button to split timing.** On the data entry form, **record:**

   - **'time' elapsed since the start**

   → Ask participant to read aloud the HR displayed on receiver watch. **Record *'HR'*** on the data entry form.

   → When appropriate, ask participant ***'how hard do you feel you are exercising?'*. Record *'RPE'*** on data entry form.

   → **Advise participant of the number of laps completed** and provide standardised encouragement:

   "2 laps down, well done/excellent/good/you're doing well/that's great."

   → Once the participant has just 4 laps to go, **advise of the number remaining:**

   "4 laps to go, well done/excellent/good/you're doing well/that's great."

4. At 1 mile (1609 meters):

   → Press the stopwatch button to split timing and **record *'final time'*** on the data entry sheet.

   → Ask participant to read aloud the ***'HR'*** and **record** this on the data entry sheet.

   → Ask for **RPE of final lap** and for the **overall walk. Record *'RPE'*** on data entry form.

   → Check participant is ok and advise them to walk one or two laps at a slower pace to cool down.

After the test:

1. **Complete the *'final data'* section** on the data entry form.

   → **Record** the **final time, HR, lap, and distance walked.**

   → **Record** whether **1 mile was completed.** If not completed, record code (see page 4).

2. Once HR has stabilised, encourage participant to ***perform stretches*** for the hamstrings, quadriceps and calves. Perform these stretches with the participant and offer verbal instruction.
3. Retrieve HR transmitter strap and receiver watch. **Tick appropriate *box*** on data entry form.
4. If feedback is requested, give participant **Time taken** to complete test, and their **%HR_{max}** during the test.
5. **Provide ActiGraph monitor,** ActiGraph information sheets and diary.

   → **Explain how to use** these, emphasising the importance of maintaining **usual lifestyle,** and advise participant to return monitor and diary at next nurse appointment.

   → **Record *'ActiGraph number'*** on data entry form.

6. **Provide Exercise questionnaire.** Advise that this should be completed at home and returned at next nurse appointment.
7. Offer participant use of shower and changing facilities.

Codes for fitness test

Test not started		
A1		Technical malfunction (HR monitor)
A2		Technical malfunction (Stopwatch)
A3		Physical condition
A4		Participant's request
A5		Inappropriate clothing/footwear
A6		Site problem
A7		Other

1 mile not completed	
Technical	
AA1	Technical malfunction (HR monitor)
AA2	Technical malfunction (Stopwatch)
Physical	
Cardio/respiratory	
AA3	Breathing problems
AA4	Chest/heart problems
AA5	Other
Mucsuloskeletal	
AA6	Physical condition (Muscle soreness/cramp etc.)
AA7	Physical condition (Joint pain)
AA8	Physical condition (Foot pain)
AA9	Physical condition (Previous injury)
AA10	Physical condition (Injury)
AA11	Physical tiredness
AA12	Other
Diabetes related	
AA13	Physical condition (Hypo)
AA14	Other
Other	
AA15	Other –State
Participant request	
AA16	Participant's request
Clothing	
AA17	Inappropriate footwear/clothing
Site	
AA18	Site problem
Other	
AA19	Other

Troubleshooting

Technical malfunctions

Heart rate monitor fails to record heart rate

⇒ If this occurs at the start of the test:
- Stop, and check Electrodes are damp
- Change transmitter strap
- Change receiver watch
- Restart test

⇒ If during test:
- Request that participant completes test
- Continue to record the time using the stopwatch
- Use the last HR recorded and obtain average to predict VO_2max

Stopwatch fails to record time

⇒ If this occurs at start of the test:
- Stop, try to reset stopwatch
- Use different stopwatch
- Restart test

⇒ If this occurs during test and you have another stopwatch to hand:
- Start other stopwatch immediately and record the time elapsed on the first stopwatch,
- Once participant has completed test, add times on both watches for time taken to complete mile.

⇒ If this occurs during test and you do not have another stopwatch to hand:
- Terminate test
- Use total time taken to complete the distance covered. Divide by distance (meters) and multiply by 1609 (meters) to obtain estimated time to complete 1 mile.
- Enter most recent HR into equation to predict fitness.

Indications for stopping the test:

- Onset of chest pain or angina-like symptoms
- Unusual or severe shortness of breath
- Physical or verbal manifestations of severe fatigue
- Feeling faint, lightheaded or dizzy
- Sudden musculoskeletal problems or injury
- Participant's request
- Failure of stopwatch
- Fire alarm

Hypos:

⇒ Unsure if hypo:
- Test glucose with blood glucose monitor
- If below 4mmol/L give 2 glucose tablets
- If above 4, give medium acting carbohydrate
- If normal, encourage participant to sit and recover

⇒ Feeling faint, lightheaded or dizzy:
- Advise participant to stop and sit down.
- Suggest testing glucose (See above for action)

⇒ Conscious and capable of swallowing:
- Give participant 3 glucose tablets immediately. If symptoms persist after 5-10minutes, give 2 more glucose tablets.
- When symptoms pass, encourage participant to eat medium acting carbohydrate within 10 minutes (Banana/biscuit)

⇒ Unconscious and breathing
- Loosen tight clothing
- Place in recovery position and **Call 999 & assistance from centre staff**

⇒ Unconscious and not breathing
- **Call 999 & assistance from centre staff**

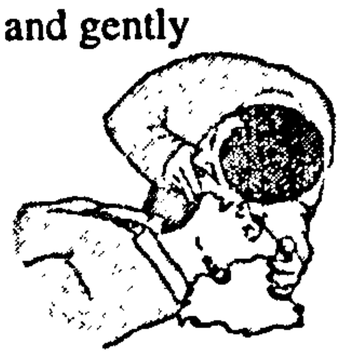
Hypo symptoms

- Weakness - Feeling faint, lightheaded or dizzy:
- Excessive sweating
- Tingling of lips, tongue or fingers
- Headache
- Becoming pale
- Intense hunger
- Irritability
- Lack of concentration
- Confusion

Time	Ideal blood glucose levels
Before meals	4-7mmol/L
2h after meals	≤ 10mmol/L

Response

If the casualty appears unconscious check this by shouting '*Can you hear me?*', '*Open your eyes*' and gently shaking their shoulders.

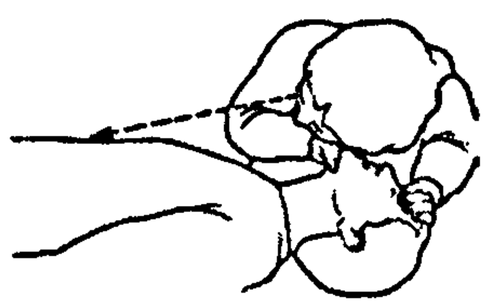


If there is no response, shout for help then follow the ABC Procedure below:

Airway

Open the airway by placing one hand on the casualty's forehead and gently tilting the head back.

Check the mouth for obstructions and then lift the chin using 2 fingers only.



Breathing

- Spend 10 seconds checking to see if the casualty is breathing:
- Look to see if the chest is rising and falling. Listen for breathing.
- Feel for breath against your cheek.

If the casualty is breathing, place them in the recovery position.

- Check for other life-threatening conditions.

For any other casualty who is not breathing, call an ambulance, then return to casualty and begin sequence again.

- Give 2 Rescue Breaths.

Circulation

Spend 10 seconds checking for signs of circulation: look, listen and feel for breathing, coughing, movement or any other signs of life.

Conscious and Breathing

- Check circulation (including a check for severe bleeding)
- Treat any injuries
- Get help if necessary

Unconscious but Breathing

- Place the casualty in the Recovery Position.
- Check circulation (including a check for severe bleeding)
- Treat any life-threatening conditions
- Call for an ambulance

Unconscious, not breathing but has circulation

- Call for an ambulance
- On return to casualty follow the resuscitation sequence again, acting on your findings.
- Check for circulation every 10 breaths.

Unconscious, not breathing and has no circulation

- If circulation is absent, and the condition is not due to injury, drowning or choking:
    - Call an ambulance, then return to casualty and follow resuscitation sequence again, acting on your findings.
- Continue to give chest compressions together with Rescue Breaths (CPR) until help arrives.

Appendix 14. Fitness test data entry form

1

FITNESS ASSESSMENT: BRISTOL EHS RUNNING TRACK
(118.4m x 13.59 laps)

Office use
Entered ⏲ Date _____
VO2max score _____ R-code _____
1 ⏲ 2 ⏲ 3 ⏲ 4 ⏲ 5 ⏲ 6 ⏲

VISIT INFORMATION

Visit ☐ Location EHS Staff ☐

Date ☐ / ☐ / 2006 Time ☐ (24 hrs)

PARTICIPANT INFORMATION

Pt. ID ☐ Nurse ☐ Centre ☐

Gender ☐ Age ☐ yrs PA rating q'nnaire ☐

HEALTH & SAFETY

PARQ information

Has participant eaten within last 3 hours? ☐ Y ☐ N If no, is blood sugar ok? _____

Is participant wearing appropriate footwear for walk test? ☐ Y ☐ N _____

Is there any other information that you should know before staring the walk test? ☐ Y ☐ N

If yes, please state _____

1 MILE WALK TEST PREPARATION

Is the HR monitor worn correctly and working? ☐ Y ☐ N

Who will read the HR during the test? ☐ Pt. ☐ Staff

Does participant understand:
The *'rating how hard you are exercising'* sheet and scale? ☐ Y ☐ N

That during the walk, they should work between 13 & 15 on the scale? ☐ Y ☐ N

How to signal for assistance or early termination? ☐ Y ☐ N

How many laps equals a mile distance? ☐ Y ☐ N

The finish point and cool down procedure? ☐ Y ☐ N

How many laps equals a mile distance? ☐ Y ☐ N

The finish point and cool down procedure? ☐ Y ☐ N

1 MILE WALK TEST DATA

%HR$_{max}$	HR
50	110
60	132
70	154
80	176
90	198
100	220

Walk test started ☐ Y ☐ N If no, record non-started code ☐☐

Time started ☐☐ : ☐☐ Pre warm-up

LAPS Completed	DISTANCE Meters	DISTANCE Miles	TIME Mins	TIME Secs	Lap Time	HR (bpm)	RPE	LAPS to go	COMMENTS
Post W-U	118.4							13.59	
1	118.40							12.6	
2	236.80							11.6	
3	355.20							10.6	
[illegible]	402.33	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	
4	473.60							9.6	
5	592.00							8.6	
6	710.40							7.6	
[illegible]	804.67	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	
7	828.80							6.6	
8	947.20							5.6	
9	1065.60							4.6	
10	1184.00							3.6	
[illegible]	1207.00	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	
11	1302.40							2.6	
12	1420.80							1.6	
13	1539.20							0.6	
13.59	1609.34							0	
						Overall rating		0	

FINAL DATA

Time ☐☐ : ☐☐ HR ☐☐☐ bpm Lap ☐☐ Distance ☐☐☐ m

1-Mile completed ☐ Y ☐ N If no, record non-completion code ☐☐☐

Polar HR monitor removed ☐ Y ☐ N

Was participant offered stretches? ☐ Y ☐ N

Comments _____

ACTIGRAPH

ActiGraph No. ☐☐☐☐☐☐ or, not provided code ☐☐

Have the Information sheets and diary been provided? ☐ Y ☐ N _____

Have the exercise questionnaires been provided? ☐ Y ☐ N _____

Appendix 15. Bivariate correlations between demographic, physiological, metabolic, cardiorespiratory fitness and physical activity variables at baseline

		Gender	Age	Height	Weight	BMI	Waist	SBP	DBP	HbA1c	TC	TG	HDL	LDL	Glucose	Insulin	HOMA	Mile time	VO2max	CPM	MVPA†
Gender	Correlation	1	0.083	0.705**	0.175**	-0.261**	0.158*	0.156**	0.023	-0.04	-0.147**	0.054	-0.278**	-0.08	-0.005	-0.037	-0.05	-0.387**	0.56**	0.113*	0.137*
	N	340	340	340	340	340	230	335	335	335	336	336	336	328	334	332	332	318	237	321	321
Age	Correlation		1	-0.066	-.285**	-.262**	-.147*	.243**	-.124*	-0.094	-0.055	-0.035	.219**	-.142**	-.159**	-.209**	-.228**	.401**	-.348**	-.283**	-.154*
	N		340	340	340	340	230	335	335	335	336	336	336	328	334	332	332	318	237	321	321
Height m	Correlation			1	.409**	-.198**	.237**	0.072	-0.003	-0.064	-0.091	0.046	-.265**	-0.019	-0.002	0.023	0.004	-.306**	.369**	.139*	.186**
	N			340	340	340	230	335	335	335	336	336	336	328	334	332	332	318	237	321	321
Weight kg	Correlation				1	.807**	.838**	-0.035	0.036	0.023	-0.087	0.053	-.247**	-0.02	-0.021	.452**	.383**	0.032	-.163**	-0.089	-0.086**
	N				340	340	230	335	335	335	336	336	336	328	334	332	332	318	237	321	321
BMI	Correlation					1	.743**	-0.096	0.041	0.076	-0.037	0.035	-0.103	-0.012	-0.006	.458**	.405**	.243**	-.449**	-.203**	-.205**
	N					340	230	335	335	335	336	336	336	328	334	332	332	318	237	321	321
Waist	Correlation						1	0.057	0.129	.161*	-0.019	0.011	-.184**	0.056	0.112	.505**	.456**	.180**	-.241**	-.208**	-0.135*
	N						230	230	230	230	230	230	230	226	229	228	228	215	161	220	220
SBP	Correlation							1	.559**	-0.021	0.014	0.029	0.027	-0.013	-0.016	-0.031	-0.031	0.032	-0.036	0.019	0.008
	N							335	335	334	335	335	335	327	333	331	331	313	236	318	318
DBP	Correlation								1	0.07	0.104	0.035	0.021	0.089	0.084	0.078	0.087	0.028	-0.032	0.01	0.015
	N								335	334	335	335	335	327	333	331	331	313	236	318	318
HbA1c	Correlation									1	.114*	0.106	0.001	0.073	.724**	0.056	.272**	0.072	-0.046	-0.083	-0.131
	N									335	335	335	335	327	334	332	332	313	235	318	318
TC	Correlation										1	.355**	.160**	.912**	.116*	-0.02	0.019	0.031	-0.087	0.088	0.030
	N										336	336	336	328	334	332	332	314	236	319	319
TG	Correlation											1	-.393**	.144**	.147**	.180**	.218**	-0.008	0.016	-0.056	-0.111*
	N											336	336	328	334	332	332	314	236	319	319
HDL	Correlation												1	-0.042	-0.007	-.228**	-.214**	.165**	-.203**	0.024	-0.015
	N												336	328	334	332	332	314	236	319	319
LDL	Correlation													1	0.042	-0.056	-0.048	0.050	-0.033	.132*	0.085
	N													328	326	324	324	306	230	311	311
Glucose	Correlation														1	0.062	.385**	-0.107	0.064	0.045	0.027
	N														334	332	332	312	234	317	317
Insulin	Correlation															1	.921**	.166**	-.175**	-.177**	-.125*
	N															332	332	290	233	315	315
HOMA	Correlation																1	.109*	-.144*	-.144*	-0.142*
	N																332	310	233	315	315
Mile time	Correlation																	1	-.850**	-.415**	-.411**
	N																	318	237	301	301
Vo2max	Correlation																		1	.389**	.347**
	N																		237	226	226
CPM	Correlation																			1	.729**
	N																			321	321
MVPA†	Correlation																				1
	N																				321

TC, Total cholesterol; TG, Triglycerides; HDL, High-density lipoprotein cholesterol; LDL, low-density lipoprotein cholesterol; CPM, counts per minute; MVPA, Minutes of moderate to vigorous physical activity; MS, metabolic syndrome; † Spearman correlation due to non-parametric data; ** P<0.01, * P<0.05

Appendix 16. Training undertaken during PhD

Course Title	Organising body	Dates
Multivariate statistical methods	University of Bristol	3hrs weekly, January-March 2007
Good Practice in clinical research	United Bristol Healthcare trust	7hrs weekly, November-December 2006
Statistics in education	University of Bristol	3hrs weekly lectures, October-December 2006
Presentations and publication	United Bristol Healthcare trust	1 day, March 2006
Data management for research data analysis	United Bristol Healthcare trust	1 day, March 2006
Protocol, ethics and project management	United Bristol Healthcare trust	1 day, February 2006
Questionnaire design	United Bristol Healthcare trust	1 day, February 2006
MS Access training	University of Bristol	1 day, January 2006
Research training	United Bristol Healthcare trust	1 day, January 2006
Publisher XP	University of Bristol	1 day, June 2005
Project management	University of Bristol	1 day, June 2005
Motivational interviewing in health and social care: Practitioner workshop	Dr. Stephen Rollnick & Dr. Gary Rose	2 days, June 2005
Physical activity counselling in general and clinical populations workshop	Bases, University of Dundee	1 day, November 2004

Appendix 17. Conference contributions and publications resulting from PhD work

Presentations

American College of Sports Medicine (2007): Physical activity and cardiorespiratory fitness in adults with newly diagnosed Type 2 Diabetes: The Early ACTID Study (Poster)

Diabetes UK Annual Professional Conference (2007): Physical activity in adults with newly diagnosed Type 2 diabetes: The Early ACTID Study (Poster)

Diabetes UK Primary Care Conference (2005): One touch empowerment developed (Workshop leader)

Publications

Fitzsimons KJ, Cooper AR, Andrews R. (2007) Physical activity and cardiorespiratory fitness in adults with newly diagnosed Type 2 diabetes: The Early ACTID Study. *Medicine and Science in Sports and Exercise* 39(5):S236

Fitzsimons KJ, Cooper AR, Andrews R. (2007) Physical activity in adults with newly diagnosed Type 2 diabetes: The Early ACTID Study. *Diabetic Medicine* 24(S1):64